AVIBELA

SCHEDULING STATUS S4

1. NAME OF THE MEDICINE
AVIBELA levonorgestrel 52 mg intrauterine delivery system

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
The active substance is levonorgestrel.

Each sterile levonorgestrel-releasing intrauterine system contains 52 mg of levonorgestrel. The initial release of levonorgestrel is approximately 20 micrograms per day. This rate decreases progressively to approximately 8,6 micrograms/day after 6 years. The average *in vivo* release rate of levonorgestrel is approximately 14,3 micrograms/day over a period of 6 years.

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM
Intrauterine delivery system (IUD) consisting of a white reservoir covered with a membrane on the vertical stem of a T-frame; a double blue thread is attached to the eyelet on the T-frame; the vertical stem of the T-frame and the thread are placed in the inserter tube, which is graduated from 5 - 12. The thread is located inside along the full length of the inserter and exits out the back end of the handle. The IUD and single-handed inserter are packaged in a thermoformed tray with a lid.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
Contraception.
Treatment of heavy menstrual bleeding. AVIBELA may be particularly useful in women with heavy menstrual bleeding requiring (reversible) contraception.

4.2 Posology and method of administration
Posology
One unit is inserted into the uterine cavity.
AVIBELA is effective for six years in the indications for contraception and heavy menstrual bleeding. Therefore, it should be removed after 6 years of use. If the user wishes to continue using the same method, a new system can be inserted at the same time. If pregnancy is not desired, AVIBELA can be removed at any time; however, a contraception method should be started prior to removal of AVIBELA. Counsel your patient that she is at risk of pregnancy if she has intercourse in the week prior to removal without use of a backup contraceptive method. Removal may be associated with some pain and/or bleeding or vasovagal reactions (e.g. syncope, bradycardia, or seizure), especially in patients with a predisposition to these conditions.

Starting Treatment
In women of fertile age, AVIBELA is inserted into the uterine cavity within seven days of the onset of menstruation. It can be replaced by a new system at any time of the cycle. AVIBELA can also be inserted immediately after a first trimester abortion. If AVIBELA is not inserted during the first 7 days of the menstrual cycle and if the provider can be reasonably certain the woman is not pregnant, abstinence or a barrier method of contraception (such as condoms and spermicide) should be used for 7 days to prevent pregnancy.
Post-partum insertion: To reduce the risk of perforation, postpartum insertions should be postponed until the uterus is fully involuted. Do not insert earlier than six weeks after delivery. If the patient is experiencing significant post-partum bleeding and/or pain then infection or other causes should be excluded before insertion.

Timing of Insertion
Refer to Table 1 for instructions on when to start use of AVIBELA.

Table 1: When to insert AVIBELA

Starting AVIBELA in women not currently using hormonal or intrauterine contraception	• AVIBELA can be inserted any time the provider can be reasonably certain the woman is not pregnant. Consider the possibility of ovulation and conception prior to initiation of this product • if AVIBELA is inserted after the first 7 days of the menstrual cycle, the patient should use a barrier method of contraception (such as condoms and spermicide) or abstain from vaginal intercourse for 7 days after insertion to prevent pregnancy.
Switching to AVIBELA from an oral, transdermal or vaginal hormonal contraceptive	• AVIBELA may be inserted at any time. ◆ may be inserted during the hormone-free interval of the previous method ◆ if inserted during active use of the previous method, continue that method for seven days after AVIBELA insertion or until the end of the current treatment cycle. • if using continuous hormonal contraception, discontinue that method seven days after AVIBELA insertion.
Switching to AVIBELA from an injectable progestin contraceptive	• AVIBELA may be inserted at any time • if AVIBELA is inserted more than 3 months (13 weeks) after the last injection, a barrier method of contraception (such as condoms and spermicide) should also be used for 7 days after insertion.
Switching to AVIBELA from a contraceptive implant or another IUD	• insert AVIBELA on the same day the implant or IUD is removed • AVIBELA may be inserted at any time during the menstrual cycle.
Inserting AVIBELA after abortion or miscarriage	
• *First-trimester*	• AVIBELA may be inserted immediately after a first-trimester abortion or miscarriage.
• *Second-trimester*	• do not insert AVIBELA until a minimum of 4 weeks after second-trimester abortion or miscarriage, or until the uterus is fully involuted. If involution is delayed, wait until involution is complete before insertion • if the woman has not yet had a period, consider the possibility of ovulation and conception occurring prior to insertion of AVIBELA. AVIBELA can be inserted any time the provider can be reasonably certain the woman is not pregnant • if AVIBELA is not inserted during the first 7 days of the menstrual cycle, a barrier method of contraception should be used or the patient should abstain from vaginal intercourse for 7 days after insertion to prevent pregnancy.
Inserting AVIBELA after childbirth	• do not insert AVIBELA until a minimum of 4 weeks after delivery, or until the uterus is fully involuted. If involution is delayed, wait until involution is complete before insertion • if the woman has not yet had a period, consider the possibility of ovulation and conception occurring prior to insertion of AVIBELA. AVIBELA can be inserted any time the provider can be reasonably certain the woman is not pregnant • if AVIBELA is not inserted during the first 7 days of the menstrual cycle, a barrier method of contraception should be used or the patient should abstain from vaginal intercourse for 7 days after insertion to prevent pregnancy • there appears to be an increased risk of perforation in lactating women.

Paediatric population
AVIBELA has not been studied in patients below 16 years of age. AVIBELA is not indicated for use before menarche.

Special populations
Elderly
AVIBELA has not been studied in elderly women.

Hepatic impairment
AVIBELA is contraindicated in patients with liver tumour or acute or severe liver disease (see section 4.3). AVIBELA has not been studied in women with hepatic impairment.

Method of administration
Instructions for use and handling
AVIBELA is supplied in a tray, sealed with a peel-off lid and is inserted into the uterine cavity with the provided inserter (Figure 1b) by carefully following the insertion instructions. Do not use if the seal of the sterile package is broken or appears compromised. Use strict aseptic techniques throughout the insertion procedure (see section 4.4 – Pelvic infection). AVIBELA is for single use only.

Figure 1a: Intrauterine contraceptive system (IUD)

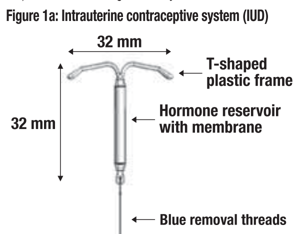
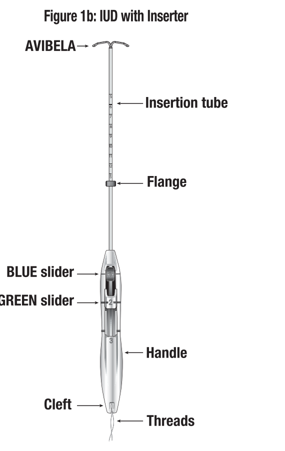


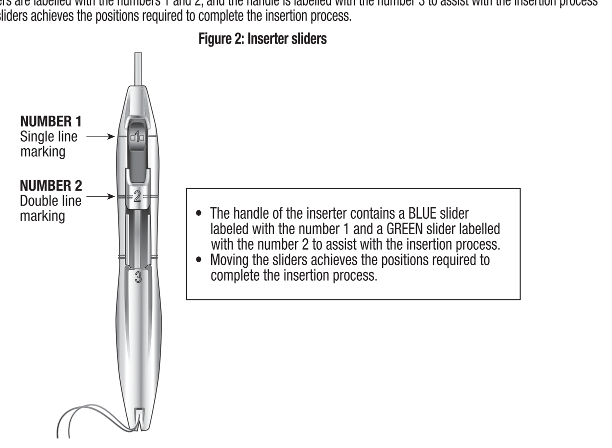
Figure 1b: IUD with Inserter



The AVIBELA IUD is packaged partially preloaded within the inserter. The threads are passed through the insertion tube and exit through an opening in the handle at the cleft.

The handle of the inserter contains a BLUE slider labelled with the number 1 and a GREEN slider labelled with the number 2. The handle is labelled with the number 3. The sliders are labelled with the numbers 1 and 2, and the handle is labelled with the number 3 to assist with the insertion process (Figure 2). Moving the sliders achieves the positions required to complete the insertion process.

Figure 2: Inserter sliders



How to insert AVIBELA
AVIBELA should only be inserted by a trained healthcare provider. Healthcare providers should become thoroughly familiar with the product, product educational materials, product insertion instructions, prescribing information, and patient labelling before attempting insertion.
- obtain a complete medical and social history to determine conditions that might influence the selection of a levonorgestrel-releasing intrauterine system for contraception. If indicated, perform a physical examination and appropriate tests for genital or sexually transmitted infections (STIs)
- check the expiration date on the box before opening it. Do not insert after the expiration date
- visually inspect the packaging containing AVIBELA to verify that the packaging has not been damaged (e.g. torn, punctured, etc.). If the packaging has any visual damage that could compromise sterility, do not use the unit for insertion
- complete the pelvic examination, speculum placement, tenaculum placement, and sounding of the uterus before opening the pouch
- do not open the packaging to insert AVIBELA if the cervix is unable to be properly visualised, if the uterus cannot be adequately instrumented (during sounding), or if the uterus sounds to less than 5,5 cm
- in case of difficult insertion and/or exceptional pain or bleeding during or after insertion, please refer to section 4.4
- AVIBELA is supplied sterile having been sterilised with ethylene oxide. Do not resterilise. For single use only. Do not use if the inner package is damaged or open. Insert before the end of the month shown on the label
- AVIBELA is inserted with the provided inserter (Figure 2) into the uterine cavity by carefully following the insertion instructions.

The following insertion instruction will be provided in the box containing the IUD.

Please read the following instructions for use carefully as there may be some difference in the type of inserter device compared with other IUDs you have used previously.

Planning for Insertion
- ensure all needed items for AVIBELA insertion are readily available:
  - gloves
  - sterile speculum
  - sterile uterine sound
  - sterile tenaculum
  - antiseptic solution
  - AVIBELA with inserter tray, sealed with a peel-off lid
  - sterile, blunt-tipped scissors
  - additional items that may be useful could include:
    - local anaesthesia, needle, and syringe
    - sterile os finder and/or cervical dilators
    - ultrasound with abdominal probe
- exclude pregnancy and confirm that there are no other contraindications to the insertion and use of AVIBELA
- follow the insertion instructions exactly as described in order to ensure proper insertion
- if you encounter cervical stenosis at any time during uterine sounding or AVIBELA insertion, use cervical dilators, not force, to overcome resistance. If necessary, dilation, sounding, and insertion may be performed with ultrasound guidance
- insertion may be associated with some pain and/or bleeding or vasovagal reactions (e.g. diaphoresis, syncope, bradycardia, or seizure), especially in patients with a predisposition to these conditions. Consider administering analgesics prior to insertion.

Use aseptic technique during the entire insertion procedure. Loading and inserting AVIBELA does not require sterile gloves. If not using sterile gloves, maintain sterility during AVIBELA loading and insertion; do not touch AVIBELA, the inside of the sterile tray, or parts of any sterile instrument that will pierce tissue (e.g. a tenaculum on the cervix) or go into the uterine cavity. If, at any step, there is a need to touch a sterile surface, sterile gloves should be used.

Preparation for insertion
The overall insertion process is conducted in 5 steps.

Step 1 – Preparation of patient for insertion
- with the patient comfortably in lithotomy position, do a bimanual exam to establish the size, shape, and position of the uterus and to evaluate any signs of uterine infection
- gently insert a speculum to visualize the cervix
- thoroughly cleanse the cervix and vagina with antiseptic solution
- administer cervical anaesthetic, if needed
- apply a tenaculum to the cervix and use gentle traction to align the cervical canal with the uterine cavity. Keep the tenaculum in position and maintain gentle traction on the cervix throughout the insertion procedure
- carefully sound the uterus to measure its depth
- the uterus should sound to a depth of at least 5,5 cm. Insertion of AVIBELA into a uterine cavity that sounds to less than 5,5 cm may increase the incidence of expulsion, bleeding, pain, perforation, and possibly pregnancy. AVIBELA should not be inserted if the uterus sounds to less than 5,5 cm
- after ascertaining that the patient is appropriate for AVIBELA, open the packaging containing AVIBELA.

IMPORTANT!
In case of difficult insertion and/or exceptional pain or bleeding during or after insertion, physical examination and ultrasound should be performed immediately to exclude perforation of the uterine body or cervix. If necessary, remove the system and insert a new, sterile system.

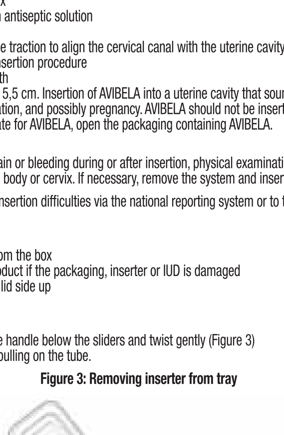
Please report any case of uterine perforation or insertion difficulties via the national reporting system or to the supplier.

Insertion procedure
Step 2 – Opening the sterile AVIBELA packaging
- remove the sealed tray containing AVIBELA from the box
- inspect the sealed tray and do not use the product if the packaging, inserter or IUD is damaged
- lay the tray on a flat surface with the peel-off lid side up
- remove peel-off lid.

Step 3 – Loading AVIBELA into the inserter
- to remove the inserter from the tray, grasp the handle below the sliders and twist gently (Figure 3)

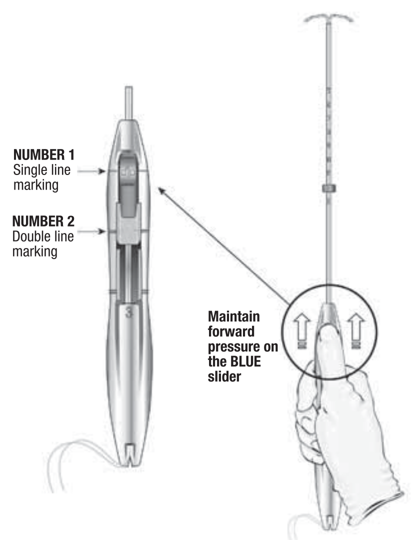
NOTE: Do not attempt to remove the inserter by pulling on the tube.

Figure 3: Removing inserter from tray



- ensure both sliders (labelled 1 and 2) are **fully forward** (Figure 4):
  - the BLUE slider (labelled with the number 1) has a single line marking that will align with the handle's single line marking
  - the GREEN slider (labelled with the number 2) has a double line marking that will align with the handle's double line marking.
- grip the handle keeping your thumb or finger in the groove of the BLUE slider (over the numeral 1) and apply **forward pressure** while ensuring both sliders are **fully forward**.

Figure 4: Sliders completely forward for loading AVIBELA



- load AVIBELA into the inserter:
  - ensure the arms of the IUD are horizontal (aligned to the horizontal plane of the handle and flange); adjust the rotation of the IUD as needed using the flat sterile surface of the tray
  - while maintaining **forward pressure** on the BLUE slider, gently pull the threads **straight** back to load AVIBELA into the insertion tube. Ensure even tension is applied to both threads when pulling
  - pull the threads upward or downward to lock the threads into the cleft at the bottom end of the handle (Figure 5); you must **lock the threads** in the cleft to prevent the IUD from moving out of the top of the insertion tube. Once the threads are locked in the cleft, **stop holding the threads**
  - after the IUD is loaded, continue to sustain **forward pressure** on the BLUE slider to maintain a hemispherical dome with the tips of the IUD.
  - when correctly loaded, the IUD is completely within the insertion tube with the tips of the arms forming a hemispherical dome at the top of the tube (Figure 6)
  - if the IUD is not correctly loaded, ***do not attempt insertion***
  - to re-load AVIBELA:
    - pull the BLUE slider back with your thumb until the groove becomes aligned with the GREEN slider to release the IUD
    - manually pull the threads out of the cleft
    - return the BLUE slider to the forward position and repeat the loading steps.

Figure 5: Locking the threads in cleft

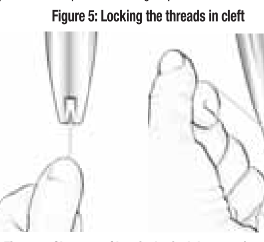
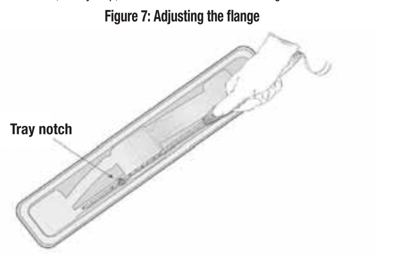


Figure 6: Close-up of hemispherical dome at tip of tube

- adjust the flange to the measured uterine depth based on sounding. To adjust, place the flat side of the flange in the tray notch (Figure 7) or against a sterile edge inside of the tray. Slide the insertion tube as necessary to move the flange to the correct measurement. Ensure the flat sides of the flange are in the same horizontal plane as the handle. If, at any step, there is a need to touch the flange or another sterile surface, sterile gloves should be used

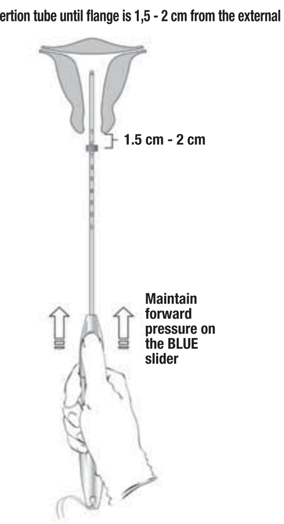
Figure 7: Adjusting the flange



- if an adjustment to the curvature of the insertion tube is required to accommodate the anatomical orientation of the uterus, you may bend or straighten the insertion tube, but do not touch above the flange unless using sterile gloves. When bending the tube, avoid sharp bends to prevent kinking
- once the flange has been properly positioned, avoid contact with flange against objects that can change its position (e.g. tray, speculum, tenaculum, etc.).

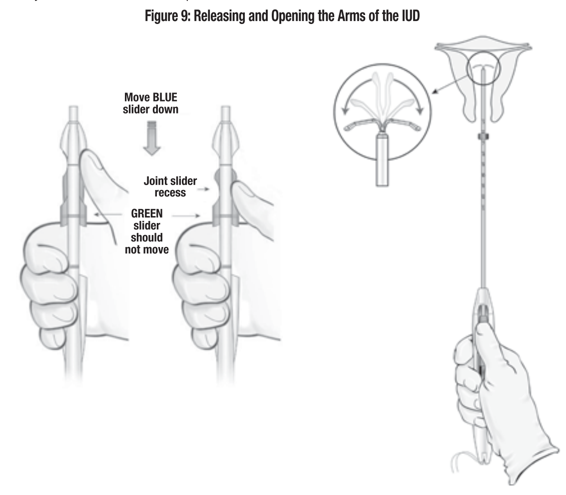
Step 4 – Inserting AVIBELA into the uterus
- apply gentle traction on the tenaculum and continue to apply **forward pressure** on the BLUE slider while inserting the loaded insertion tube through the cervical os. Advance the tube until the upper edge of the flange is 1,5 - 2 cm from the external cervical os (Figure 8). Maintain forward pressure on the BLUE slider throughout the insertion process.
  - DO NOT advance flange to the cervix at this time
  - DO NOT force the inserter. If necessary, dilate the cervical canal.

Figure 8: Advancing insertion tube until flange is 1,5 - 2 cm from the external cervix



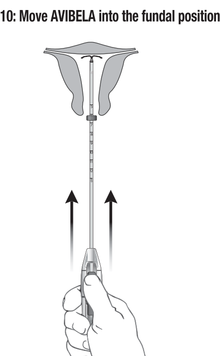
- using your thumb or finger, gently slide only the BLUE slider back. You will feel slight resistance initially to move the BLUE slider out of its starting position. Continue to move the BLUE slider back until you feel slight resistance again as the BLUE and GREEN sliders will merge together to form a joint slider recess. Do not move the BLUE slider any more than is necessary to create the recess. Maintain the GREEN slider so that the double line markings on the slider and the insertion handle remain aligned (Figure 9). This will allow the IUD arms to open in the lower uterine segment. Do not pull the sliders back any further as this could result in premature release of the IUD at the incorrect location

Figure 9: Releasing and Opening the Arms of the IUD



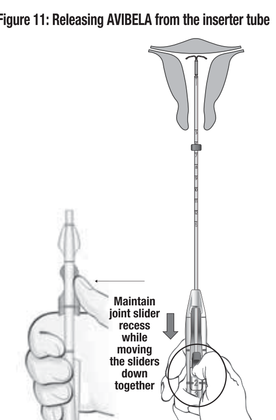
- wait 10 - 15 seconds to allow for the arms of the IUD to fully open
- without moving the sliders, advance the inserter until the flange touches the cervix. If fundal resistance is encountered, do not continue to advance. AVIBELA is now in the fundal position (Figure 10)
- note: Fundal position is important to prevent expulsions.

Figure 10: Move AVIBELA into the fundal position



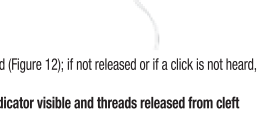
Step 5 – Releasing AVIBELA and procedure completion
While holding the inserter steady and maintaining its position relative to the cervix, move **both** sliders (BLUE and GREEN) together while maintaining the joint slider recess down toward the number 3 on the handle (Figure 11) until a click is heard and the GREEN indicator at the bottom of the handle is visible, signifying deployment (Figure 12).

Figure 11: Releasing AVIBELA from the inserter tube



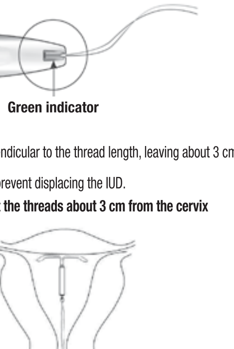
- look at the cleft to ensure the threads were properly released (Figure 12); if not released or if a click is not heard, grasp the threads and gently pull the threads out of the cleft

Figure 12: Green indicator visible and threads released from cleft



- withdraw the inserter from the uterus
- use blunt-tipped sharp scissors to cut the IUD threads perpendicular to the thread length, leaving about 3 cm outside of the cervix (Figure 13). *Note: Do not cut threads at an angle as this may leave sharp ends*
- do not apply tension or pull on the threads when cutting to prevent displacing the IUD.

Figure 13: Cut the threads about 3 cm from the cervix



- insertion of AVIBELA is now complete.

Important information to consider during or after insertion:
If you suspect the IUD is not in the correct position:
- check insertion with an ultrasound or other appropriate radiologic test
- if incorrect insertion is suspected, remove AVIBELA. Do not reinsert the same AVIBELA IUD after removal.

Difficult insertion
- if insertion is difficult because the uterus cannot be appropriately instrumented, the following measures can be considered:
  - use of cervical anaesthesia to make sounding and manipulation more tolerable
  - use of dilators to dilate the cervix if needed to allow passage of the sound
  - abdominal ultrasound guidance during dilation and/or insertion
  - if there is clinical concern, exceptional pain, or bleeding during or after insertion, take appropriate steps, such as physical examination and ultrasound, immediately to exclude perforation.

Patient counselling and record-keeping
- counsel the patient on what to expect following AVIBELA insertion. Review the signs and symptoms of expulsion
- prescribe analgesics, if indicated.

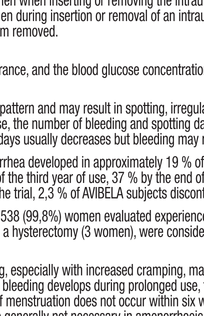
Patient follow-up
Re-examine and evaluate patients 4 - 6 weeks after insertion and once a year thereafter, or more frequently if clinically indicated. The healthcare provider should check strings during each routine and follow-up visit.

Removal of AVIBELA
Timing of removal
- if pregnancy is desired, AVIBELA can be removed at any time
- if pregnancy is not desired, AVIBELA can be removed at any time; however, a contraception method should be started prior to removal of AVIBELA. Counsel your patient that she is at risk of pregnancy if she has intercourse in the week prior to removal without use of a backup contraceptive method
- AVIBELA should be removed after 6 years. AVIBELA can be replaced at the time of removal with a new AVIBELA if continued contraceptive protection is desired.

Planning for removal
- Ensure all needed items for AVIBELA removal are readily available:
  - gloves
  - sterile speculum
  - sterile forceps
  - additional items that may be required could include:
    - local anaesthetic, needle, and syringe
    - sterile os finder and/or cervical dilators
    - ultrasound with abdominal probe
    - sterile tenaculum
    - antiseptic solution
    - sterile long, narrow forceps or intrauterine thread retriever
- removal may be associated with some pain and/or bleeding or vasovagal reactions (e.g. syncope, bradycardia, or seizure), especially in patients with a predisposition to these conditions
- after removal of AVIBELA, examine the system to ensure that it is intact.

Removal instructions
- with the patient comfortably in lithotomy position, place a speculum and visualise the cervix
- when the threads of AVIBELA are visible:
  - remove the IUD by applying traction on the threads with forceps (Figure 14)
  - the arms of the device will fold upward as it is withdrawn from the uterus
  - if the IUD cannot be removed with traction on the threads, perform an ultrasound examination to confirm location of the IUD, including assessment for partial or total perforation. If the IUD is in the uterus, use a long, narrow forceps to grasp AVIBELA. Consider use of a tenaculum, cervical anaesthesia, cervical dilators, and/or ultrasound guidance as needed
  - after removal, examine the system to ensure it is intact.
- if the threads of AVIBELA are not visible:
  - determine location of the IUD by ultrasound examination
  - if the IUD is in the uterine cavity, thoroughly cleanse the cervix and vagina with antiseptic solution. Use a thread retriever to capture the threads or a long, narrow forceps (e.g. Alligator forceps) to grasp AVIBELA. Consider use of a tenaculum, cervical anaesthesia, cervical dilators, and/or ultrasound guidance as needed. If AVIBELA cannot be removed using the above techniques, consider hysteroscopic evaluation for removal
  - if the IUD is not in the uterine cavity, consider an abdominal x-ray or CT scan to evaluate if the IUD is in the abdominal cavity. Consider laparoscopic evaluation for removal, as clinically indicated
  - after removal, examine the system to ensure it is intact.

Figure 14: Removal of AVIBELA



Continuation of contraception after removal
- if a patient wishes to continue using AVIBELA or another intrauterine contraceptive, insertion can occur immediately after removal
- if a patient with regular cycles wants to start a different birth control method, time the removal and initiation of a new method to ensure continuous contraception. Either remove AVIBELA during the first 7 days of the menstrual cycle and start the new method or start the new method at least 7 days prior to removing AVIBELA if removal is to occur at other times during the cycle
- if a patient with irregular cycles or amenorrhea wants to start a different birth control method, start the new method at least 7 days before AVIBELA removal
- if AVIBELA is removed but no other contraceptive method has already been started, the new contraceptive method can be started on the day AVIBELA is removed. The patient should use a backup barrier method of contraception (e.g. condoms and spermicide) or abstain from vaginal intercourse for 7 days to prevent pregnancy.

4.3 Contraindications
AVIBELA is contraindicated in the following conditions:
- hypersensitivity to levonorgestrel or to any of the ingredients of AVIBELA listed in section 6.1
- known or suspected pregnancy
- lower genital tract infection
- current or recurrent pelvic inflammatory disease or conditions associated with increased risk of pelvic infections, including gonorrhoea and other sexually transmitted infections
- postpartum endometritis
- infected abortion during the past three months
- acute cervicitis or vaginitis
- cervical dysplasia or neoplasm
- uterine or cervical malignancy
- progestogen-dependent tumours, known or suspected breast cancer or other hormone-sensitive cancer, now or in the past (see section 4.4)
- undiagnosed abnormal uterine bleeding
- congenital or acquired uterine anomaly including fibroids which would interfere with insertion and/or retention of the intrauterine system i.e. if they distort the uterine cavity
- acute or severe liver disease or liver tumour
- a previously inserted IUD that has not been removed
- conditions associated with increased susceptibility to infections
- acute malignancies affecting the blood or leukaemia except when in remission
- recent trophoblastic disease while human chorionic gonadotropin (hCG) levels remain elevated.

4.4 Special warnings and precautions for use
Medical examination
Obtain a complete medical and social history, including partner status, to determine conditions that might influence the selection of an IUD for contraception and/or heavy menstrual bleeding.

Before insertion, the woman must be informed of the benefits and risks of AVIBELA. Exclude underlying endometrial pathology (e.g. polyps or cancer) prior to the insertion of AVIBELA in women with persistent or uncharacteristic bleeding because irregular bleeding/spotting is common during the first months of AVIBELA use and may preclude adequate assessment after insertion. AVIBELA is contraindicated in women with uterine bleeding of unknown aetiology. Exclude underlying congenital or acquired uterine anomalies, including fibroids, that distort the uterine cavity and would be incompatible with correct IUD placement.
Ensure a previously inserted IUD has been removed prior to insertion of AVIBELA.
Assess whether the woman is at increased risk of infection (e.g. leukaemia, acquired immune deficiency syndrome [AIDS], intravenous [IV] substance abuse), or has a history of pelvic inflammatory disease (PID) unless there has been a subsequent intrauterine pregnancy. AVIBELA does not protect against human immunodeficiency virus (HIV)/STI transmission.

Conditions under which AVIBELA can be used with caution
- use AVIBELA with caution after careful assessment if any of the following conditions exist, and consider removal of the IUD if any of them arise during use: migraine, focal migraine with asymmetrical visual loss or other symptoms indicating transient cerebral ischaemia
- exceptionally severe or frequent headache
- marked increase of blood pressure
- severe arterial disease such as stroke or myocardial infarction
- coagulopathy or use of anticoagulants.

Consider removing AVIBELA if any of the following conditions arise during use:
- uterine or cervical malignancy
- jaundice.

Vascular effects
In women using progestogen-only pills some recent epidemiological studies indicated that there may be a slightly increased risk of venous thromboembolism, but the results were statistically not significant. However, appropriate diagnostic and therapeutic measures should be undertaken immediately if there are symptoms or signs of thrombosis. Symptoms of venous or arterial thrombosis can include: unilateral leg pain and/or swelling; sudden severe pain in the chest, whether or not it radiates to the left arm; sudden breathlessness; sudden onset of coughing; any unusual, severe, prolonged headache; sudden partial or complete loss of vision; diplopia; slurred speech or aphasia; vertigo; collapse with or without focal seizure; weakness or very marked numbness suddenly affecting one side or one part of the body; motor disturbances; "acute" abdomen. Symptoms or signs indicating retinal thrombosis are: unexplained partial or complete loss of vision, onset of proptosis or diplopia, papilledema, or retinal vascular lesions. There is no consensus about the possible role of progestogens in patients with varicose veins and superficial thrombophlebitis in the causation of venous thromboembolism.

Cardiac effects
AVIBELA may be used with caution in women who have congenital heart disease or valvular heart disease at risk of infective endocarditis. Antibiotic prophylaxis should be administered to these women when inserting or removing the intrauterine system.
Syncope or bradycardia may occur in some women during insertion or removal of an intrauterine system. In the event of early signs of a vasovagal attack, insertion may need to be abandoned or the system removed.

Blood glucose effects
Low-dose levonorgestrel may affect glucose tolerance, and the blood glucose concentration should be monitored in diabetic users of AVIBELA.

Bleeding irregularities
Use of AVIBELA can alter the menstrual bleeding pattern and may result in spotting, irregular bleeding, heavy bleeding, oligomenorrhea or amenorrhea. During the first three to six months of AVIBELA use, the number of bleeding and spotting days may increase, and irregular bleeding patterns may develop. Thereafter, the number of bleeding and spotting days usually decreases but bleeding may remain irregular.

In the AVIBELA contraception clinical trial, amenorrhea developed in approximately 19 % of AVIBELA users by the end of the first year of use, 27 % by the end of the second year of use, 37 % by the end of the third year of use, 37 % by the end of the fourth year of use, 40 % by the end of the fifth year of use, and 40 % by the end of the sixth year of use. In the trial, 2,3 % of AVIBELA subjects discontinued due to bleeding complaints.

In the AVIBELA contraception clinical trial, 537 of 538 (99,8%) women evaluated experienced menses after AVIBELA removal. This excludes fourteen women who – became pregnant (9 women), had a hysterectomy (3 women), were considered menopausal after removal (1 woman), or had ovulatory dysfunction (1 woman).

Increased menstrual flow or unexplained bleeding, especially with increased cramping, may be indicative of expulsion and clinical evaluation should be performed as indicated. If a significant change in bleeding develops during prolonged use, take appropriate diagnostic measures to rule out endometrial pathology. Consider the possibility of pregnancy if menstruation does not occur within six weeks of the onset of a previous menstruation. Once pregnancy has been excluded, repeated pregnancy tests are generally not necessary in amenorrhoeic women unless indicated, for example, by other signs of pregnancy or by pelvic pain.

Pelvic infection
Insertion of AVIBELA is contraindicated in the presence of known or suspected pelvic inflammatory disease (PID) or endometritis or a history of PID unless there has been a subsequent intrauterine pregnancy. It is also contraindicated in patients with untreated acute cervicitis or vaginitis (including bacterial vaginosis), known chlamydial or gonococcal cervical infection, or other known lower genital tract infections, until the infection is controlled. IUDs have been associated with an increased risk of PID, most likely due to organisms being introduced into the uterus during insertion. Assess risk factors for infection accordingly.

In the contraception clinical trial with AVIBELA, pelvic infection was diagnosed in 0,8 % of women. Pelvic infection was diagnosed as PID in 0,5 % of women and as endometritis in 0,3 % of women. Infections occurred following variable duration-of-use. One woman diagnosed with PID and two women diagnosed with endometritis developed the infection within a week of AVIBELA insertion. One case of endometritis was diagnosed at 39 days after AVIBELA insertion. The remaining 11 cases of PID and endometritis were diagnosed more than six months after insertion, including one at 30 days after IUD removal. Women who use AVIBELA should be counselled to promptly notify a healthcare professional if they develop lower abdominal or pelvic pain, fever, chills, unusual or malodorous discharge, unexplained bleeding, genital lesions or sores, or dyspareunia. In such circumstances, perform a pelvic examination promptly to evaluate for possible pelvic infection. Remove AVIBELA in cases of recurrent PID or endometritis, or if an acute pelvic infection is severe or does not respond to treatment.

PID and endometritis are often associated with a sexually transmitted infection (STI), and AVIBELA does not protect against STIs. The risk of PID or endometritis is greater for women who have multiple sexual partners, and for women whose sexual partner(s) have multiple sexual partners. Women who have had PID or endometritis are at increased risk for a recurrence or re-infection. Other risk factors for these infections include leukaemia, acquired immune deficiency syndrome (AIDS), and illicit intravenous substance use.
PID or endometritis may be asymptomatic but still result in tubal damage and its sequelae.

Following a diagnosis of PID or endometritis, or suspected PID or endometritis, perform appropriate testing for sexually transmitted infection and initiate antibiotic therapy promptly.
AVIBELA does not need to be removed immediately if the woman needs ongoing contraception. In the AVIBELA contraception clinical trial, 12 of the 14 women who developed PID or endometritis were successfully treated without removal of AVIBELA (one of the 14 women developed PID 30 days after removal).
Reassess the woman in 48 - 72 hours. If no clinical improvement occurs, continue antibiotics and consider removal of AVIBELA. If the woman wants to discontinue use, remove AVIBELA after antibiotics have been started to avoid the potential risk for bacterial spread resulting from the removal procedure.

Actinomycosis has been associated with IUD use. Symptomatic women with known actinomycosis infection should have AVIBELA removed and receive antibiotics. *Actinomycetes* can be found in the genital tract cultures in healthy women without IUDs. The significance of *actinomyces*-like organisms on a Pap test in an asymptomatic IUD user is unknown, and so this finding alone does not always require AVIBELA removal and treatment. When possible, confirm a Pap test diagnosis with cultures.

Expulsion
Partial or complete expulsion of AVIBELA may occur, resulting in the loss of contraceptive protection. In the contraception clinical trial with AVIBELA, an overall expulsion rate of 4,0 % over 6 years was reported, with a rate of 2,2 % in nulliparous women and 6,2 % in parous women. The majority (73,5 %) occur in the first 12 months, with 25,0 % occurring in the first three months and 44,1 % in the first six months, cumulatively. Expulsion may be associated with symptoms of bleeding or pain, or it may be asymptomatic and go unnoticed. AVIBELA typically decreases menstrual bleeding over time; therefore, an increase of menstrual bleeding may be indicative of an expulsion. Consider further diagnostic imaging, such as sonography or X-ray, to confirm expulsion if AVIBELA is not found in the uterus.
The risk of expulsion may be increased when the uterus is not completely involuted at the time of insertion. Delay AVIBELA insertion a minimum of 4 weeks or until uterine involution is complete following a delivery or a second trimester abortion.

Perforation
Perforation (total or partial, including penetration/embedment of AVIBELA in the uterine wall or cervix) may occur, most often during insertion, although the perforation may not be detected until sometime later. Perforation may reduce contraceptive efficacy and result in pregnancy. This may be associated with severe pain and continued bleeding. The incidence of perforation during or following AVIBELA insertion in the clinical trial for contraception, which excluded breastfeeding women, was 0,1 %.

If perforation is suspected the IUD should be removed as soon as possible; surgery may be required. Delayed detection or removal of AVIBELA in case of perforation may result in migration outside the uterine cavity, adhesions, peritonitis, intestinal perforations, intestinal obstruction, abscesses, and erosion of adjacent viscera.
In a large prospective comparative non-interventional cohort study with another IUD the incidence of uterine perforation was reported as 6,3 per 1000 insertions for lactating women, compared to 1,0 per 1000 insertions for non-lactating women.

The risk of perforation may be increased if AVIBELA is inserted when the uterus is fixed retroverted or not completely involuted during the postpartum period. Delay AVIBELA insertion a minimum of four weeks or until involution is complete following a delivery or a second trimester abortion.

Ectopic pregnancy
The absolute risk of ectopic pregnancy in users of levonorgestrel IUD is low. However, when a woman becomes pregnant with AVIBELA *in situ*, the relative likelihood of ectopic pregnancy is increased. Approximately half of pregnancies that occur with AVIBELA in place are likely to be ectopic. The possibility of ectopic pregnancy should be considered in the case of lower abdominal pain – especially in connection with missed periods or if an amenorrhoeic woman starts bleeding. If an ectopic pregnancy is confirmed, AVIBELA should be removed.
The incidence of ectopic pregnancy in the clinical trial of contraception with AVIBELA, which excluded women with a history of ectopic pregnancy who did not have a subsequent intrauterine pregnancy, was approximately 0,12 per 100 women-years. The risk of ectopic pregnancy in women who have a history of ectopic pregnancy and use AVIBELA is unknown. Women with a previous history of ectopic pregnancy, tubal surgery or pelvic infection have a higher risk of ectopic pregnancy. Ectopic pregnancy may require surgery and may result in loss of fertility.
Women who use AVIBELA should be informed about recognizing the signs and symptoms of ectopic pregnancy and promptly reporting them to their healthcare provider, and about the associated risks of ectopic pregnancy (e.g. loss of fertility).

Lost threads
If the retrieval threads are not visible at the cervix on follow-up examination, first exclude pregnancy. If pregnancy has been excluded, the threads may usually be located by gently probing the cervical canal with a suitable instrument. If they cannot be found, they may have broken off, withdrawn into the uterus, or the device may have been expelled. Ultrasound or X-ray may be used to locate the IUD.
If AVIBELA is displaced, remove it. A new AVIBELA may be inserted at that time or during the next menses if it is certain that conception has not occurred.
If AVIBELA is in place with no evidence of perforation, no intervention is indicated.

Ovarian cysts/enlarged ovarian follicles/delayed follicular atresia
Since the contraceptive effect of AVIBELA is mainly due to its local effect, ovulatory cycles with follicular rupture usually occur in women of fertile age. Sometimes atresia of the follicle is delayed and folliculogenesis may continue. Most ovarian cysts that occur during use of levonorgestrel-releasing IUDs are asymptomatic and disappear spontaneously during two to three months of observation. Ovarian cysts that cause clinical symptoms can result in pelvic or abdominal pain or dyspareunia. Symptomatic ovarian cysts occurred in 4,5 % of subjects using AVIBELA over the course of 6 years, and 0,3 % of subjects discontinued use of AVIBELA because of an ovarian cyst.
It is recommended to evaluate persistent ovarian cysts. Surgical intervention is not usually required but may be necessary in some cases. Discuss this risk with patients who choose to use AVIBELA.

Breast cancer
Women who currently have or have had breast cancer, or have a suspicion of breast cancer, should not use hormonal contraception, including AVIBELA, because some breast cancers are hormone-sensitive.
Spontaneous reports of breast cancer have been received during post-marketing experience with another LNG-releasing IUD. Observational studies have not provided consistent evidence of an increased risk of breast cancer with use of an LNG-releasing IUD.

Other
AVIBELA is not the method of first choice for postmenopausal women with advanced uterine atrophy.
Chloasma may occasionally occur, especially in women with a history of chloasma gravidarum. Women with a tendency to chloasma should avoid exposure to the sun or ultraviolet radiation whilst using AVIBELA.

4.5 Interaction with other medicines and other forms of interaction
The effect of hormonal contraceptives may be impaired by medicines which induce liver enzymes which may result in increased clearance of sex hormones.

Substances increasing the clearance of levonorgestrel include primidone, barbiturates, phenytoin, carbamazepine, rifampicin and oxcarbazepine, topiramate, felbamate, griseofulvin, rifabutin, nevirapine, efavirenz and products containing St. John's wort. The influence of these medicines on the contraceptive efficacy of AVIBELA has not been studied but is not believed to be of major importance due to the mainly local mechanisms of contraceptive action. No drug-drug interaction studies have been conducted with AVIBELA.
The contraceptive effect of AVIBELA is mediated via the direct release of levonorgestrel into the uterine cavity and is unlikely to be affected by drug interactions via enzyme induction or inhibition.

4.6 Fertility, pregnancy and lactation
Pregnancy
The use of AVIBELA during an existing or suspected pregnancy is contraindicated (see section 4.3). If the woman becomes pregnant with AVIBELA *in situ* (see section 5), advise a woman of the increased risks for pregnancy complications, including miscarriage, premature labour, premature delivery, infection and sepsis. Ectopic pregnancy should be excluded (see section 4.4) and removal of the system should be considered.
Removal of AVIBELA or probing of the uterus may result in spontaneous abortion. Should these procedures not be possible or if the woman wishes to continue the pregnancy, the woman should be informed about these risks, and accordingly, such pregnancies should be closely monitored. Prenatal care should include counselling about these risks and that she should report immediately any flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge or leakage of fluid, or any other symptom that suggests complications of the pregnancy.

Clinical experience of the outcomes of pregnancies with levonorgestrel IUD *in situ* is limited. However, to date, there is no evidence of birth defects caused by local levonorgestrel IUD use in cases where pregnancy continues to term with the IUD in place.

Breastfeeding
Levonorgestrel has been identified in the breast milk of lactating women using IUDs. The quantity and quality of breast milk are however not affected. About 0,1 % of the levonorgestrel dose passes into the breast milk in nursing mothers.

Fertility
The use of AVIBELA does not alter the course of future fertility. Upon removal of the AVIBELA, women usually return to their normal fertility (see section 4.4). In the clinical trial of women using AVIBELA for contraception, 99,8 % of women had a rapid return of menses after IUD removal. This excludes fourteen women – who became pregnant (9 women), had a hysterectomy (3 women), were considered menopausal after removal (1 woman), or had ovulatory dysfunction (1 woman). Of 191 women who desired pregnancy after study discontinuation, 79 % conceived within 6 months after removal of AVIBELA, and 85 % conceived within 12 months after removal of AVIBELA.

AVIBELA®
levonorgestrelvrystelling-intrauteriene stelsel 52 mg

AVIBELA®
levonorgestrel-releasing intrauterine system 52 mg

4.7 Effects on ability to drive and use machines
AVIBELA has no known influence on the ability to drive or use machines.

4.8 Undesirable effects
a. Summary of the safety profile
Side-effects are more common during the first months after the insertion and subside during prolonged use. Very common undesirable effects (occurring in more than 10 % of users) include vaginal bacterial infections, vulvovaginal mycotic infections, nausea or vomiting, and acne.

b. Tabulated list of adverse effects
The table below reports adverse reactions assessed as related to 52 mg levonorgestrel intrauterine delivery system by investigator, by MedDRA system organ class (MedDRA SOCs).

Organ System	Very common: ≥1/10	Common: ≥1/100 - <1/10	Uncommon: ≥1/1000 - <1/100	Rare: ≥1/10000 - <1/1000
Infections and infestations	Vaginal bacterial infections, vulvovaginal mycotic infections		Pelvic inflammatory disease, endometritis	
Psychiatric disorders		Anxiety, depression, mood changes, insomnia, libido decreased	Exacerbation of bipolar disorder	Suicidality
Nervous system disorders		Headache, migraine, presyncope, dizziness, syncope		
Gastrointestinal disorders		Abdominal pain/discomfort, abdominal distension, constipation, dyspepsia, diarrhoea, vomiting		
Skin and subcutaneous tissue disorders	Acne	Alopecia		Greasy hair, hirsuitism
Musculoskeletal and connective tissue disorders		Back pain, pain in extremity		
Pregnancy, puerperium and perinatal conditions			Ectopic pregnancy	
Reproductive system and breast disorders	Uterine/vaginal bleeding including spotting, oligomenorrhea, amenorrhea, menstrual cycle prolonged	Ovarian cysts, dysmenorrhoea, breast tenderness/pain, pelvic discomfort/pain, uterine spasm, vaginal discharge, vulvovaginal dryness/ discomfort, ovarian cyst, menorrhagia, coital bleeding, vaginal odour, vaginal haemorrhage, bleeding menstrual heavy	Parametritis, pelvic pain, salpingo-oophoritis, polymenorrhoea	
General disorders and Administration site conditions			Oedema abdomen, peripheral oedema	
Investigations		Weight increase, ultrasound ovary abnormal		
Injury, poisoning and procedural complications	Procedural bleeding	Intrauterine contraceptive device expelled, intrauterine contraceptive device migration, procedural pain	Perforation	

Cases of sepsis (including group A *streptococcal* sepsis) have been reported following insertions with hormonal IUDs (see section 4.4).

c. Description of selected adverse reactions
Changes in menstrual bleeding
The most common adverse effect of IUDs, like AVIBELA, is a change in menstrual bleeding patterns. The changes may include spotting, shorter or longer menstrual periods, irregular bleeding, oligomenorrhoea, amenorrhoea, heavy flow, back pain and dysmenorrhoea. The average number of spotting days decreased gradually during the first six months of use.

Combination with estrogen replacement therapy
When used in combination with estrogen replacement therapy, perimenopausal users of AVIBELA may experience spotting and irregular bleeding during the first months of the treatment. A non-bleeding pattern gradually develops in most women during the first year.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

4.9 Overdose
Not applicable

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Plastic IUD with progestogen
ATC code: G02BA03
Pharmacological classification: 32.9 Other – Intrauterine devices

Pharmacological action
Levonorgestrel is a progestogen with anti-estrogenic activity. The contraceptive and therapeutic effects of levonorgestrel are mainly based on local progestogenic effects in the uterine cavity. Levonorgestrel has an antiproliferative effect on the endometrium and it inhibits the endometrial synthesis of estrogen receptors, making the endometrium insensitive to the circulating estradiol. Morphological changes of the endometrium and a weak local foreign body reaction are observed. Thickening of the cervical mucous prevents passage of the sperm through the cervical canal, and the changes in the uterus and the ovarian tubes inhibit sperm mobility and function, preventing fertilisation. Ovulation is inhibited in some women.

In heavy menstrual bleeding, prevention of proliferation of the endometrium is the probable mechanism of action of AVIBELA in reducing blood loss.

Clinical Efficacy
Contraception trial
When placed according to the insertion instructions, AVIBELA offers contraceptive protection which does not appear to vary by parity, race or body mass index. Contraceptive efficacy of AVIBELA was investigated in a large clinical trial. The pregnancy rate calculated as the Pearl Index (PI) in women aged 16 - 35 years, inclusive, was the primary efficacy endpoint used to assess contraceptive reliability. The PI was calculated based on 28-day equivalent exposure cycles; evaluable cycles excluded those in which back-up contraception was used unless a pregnancy occurred in that cycle. The Year 1 PI was based on two pregnancies and the cumulative 6-year pregnancy rate was calculated by the life table method, based on a total of nine pregnancies that occurred after the onset of treatment and within 7 days after AVIBELA removal or expulsion. The cumulative pregnancy rate was 0,14 (95 % CI: 0,04; 0,57) at the end of Year 1 and the Life Table pregnancy rate was 0,87 (95 % CI: 0,44; 1,70) at the end of Year 6.

In the clinical trial of AVIBELA evaluating contraception, during the first 3 - 6 months of use, the number of bleeding and spotting days may be increased and bleeding patterns may be irregular. Thereafter, the number of bleeding and spotting days usually decreases but bleeding may remain irregular. Amenorrhea develops in approximately 19 % of AVIBELA users by the end of the first year of use, 27 % by the end of the second year of use, 37 % by the end of the third year of use, 37 % by the end of the fourth year of use, 40 % by the end of the fifth year of use, and 40 % by the end of the sixth year of use.

Following removal of AVIBELA, 99,87 % of women evaluated in the contraception study experience menses within 3 months. Of 191 women who desired pregnancy after study discontinuation, 79 % conceived within 6 months after removal of AVIBELA, and 85 % conceived within 12 months after removal of AVIBELA.

Heavy menstrual bleeding trial
In the clinical trial evaluating women with heavy menstrual bleeding (≥80 mL per menstrual cycle), AVIBELA achieved a significant reduction in menstrual blood loss within 3 - 6 months of treatment. The volume of menstrual bleeding was decreased by 88 % in women with heavy menstrual bleeding by the end of 3 months of use and 82 % reduction was sustained for the duration of the study (12 months), with 15 % becoming amenorrhoeic at the end of the first year and 29 % at the end of the third year. Heavy menstrual bleeding caused by submucosal fibroids may respond less favourably. Reduced bleeding promotes an increase of blood haemoglobin in patients with heavy menstrual bleeding.

5.2 Pharmacokinetic properties
Absorption:
The pharmacokinetics of levonorgestrel itself have been extensively studied and reported in the literature. Orally administered levonorgestrel is rapidly and completely absorbed and the absolute bioavailability is about 90 %.

Distribution:
The initial *in vivo* release rate is 20,1 micrograms/day and decreases to 17,5 micrograms/day at 1 year, 15,2 micrograms/day at 2 years, 13,2 micrograms/day at 3 years, 11,4 micrograms/day at 4 years, 9,9 micrograms/day at 5 years, and 8,6 micrograms/day at 6 years. Levonorgestrel is delivered directly into the uterine cavity with low plasma concentrations (252 ± 123 pg/mL 7 days after insertion and 93 ± 45 pg/mL after 6 years) resulting in only minor systemic effects.
Levonorgestrel is bound to serum albumin and to sex hormone-binding globulin (SHBG). The relative distribution (free, albumin-bound, SHBG-bound) depends on the SHBG concentration in the serum. Only about 2,5 % of the total serum drug levels are present as free steroid, but 47,5 % and 50 % are bound to SHBG and albumin, respectively. For levonorgestrel, a mean volume of distribution of approximately 137 litres and a metabolic clearance rate from serum of about 5,7 L/h were reported.

Biotransformation:
A terminal half-life of levonorgestrel in serum in the range of about 14 - 20 hours can be observed after single dose administration.

Elimination:
Levonorgestrel is excreted as metabolites at about equal proportions with urine and faeces. The metabolites have only weak or no pharmacological activity.
About 0,1% of the maternal dose of levonorgestrel can be transferred via milk to the infant.

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Reservoir of the IUD
Silicone base
Tetra-n-propyl silicate
Stannous octoate

T-frame
Low density polyethylene (LDPE)
Barium sulphate
Polydimethylsiloxane (PDMS) membrane
Polypropylene thread dyed with
Phthalocyaninato (2-) copper

6.2 Incompatibilities
Not applicable

6.3 Shelf life
5 years

6.4 Special precautions for storage
Store at or below 30 °C
Store in the original package. Keep the tray in the outer carton in order to protect from light.

6.5 Nature and contents of container
The AVIBELA device is supplied partially preloaded within the single-handed inserter (a single-use, disposable, sterile insertion system) and packaged in a clear plastic tray with lid. AVIBELA is available in a carton of one sterile unit.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product
As the insertion technique is different from intrauterine devices, special emphasis should be given to training in the correct insertion technique.

AVIBELA is supplied in a sterile pack which should not be opened until required for insertion. Each system should be handled with aseptic precautions. If the seal of the sterile envelope is broken, the system inside should be disposed of in accordance with the local guidelines for the handling of biohazardous waste. Likewise, a removed AVIBELA and inserter should be disposed of in this manner. The outer carton package and the inner tray can be handled as household waste.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION
Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town, South Africa
Tel: +27 21 707 7000
or 0860-PHARMA (742 762)

8. REGISTRATION NUMBER
A56/32.9/1048

9. DATE OF FIRST AUTHORISATION
18 March 2025

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S4

AVIBELA 20 micrograms/24 hours intrauterine delivery system
Levonorgestrel
Sugar free

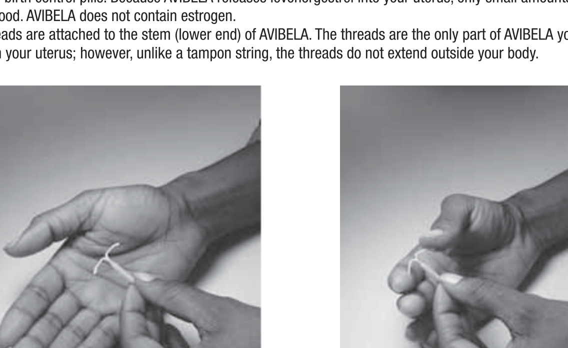
AVIBELA does not protect against human immunodeficiency virus (HIV) infection or acquired immune deficiency syndrome (AIDS) and other sexually transmitted disease (STDs).

Read all of this leaflet carefully before AVIBELA is inserted
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist. This information does not take the place of talking with your gynaecologist or other healthcare provider who specializes in women's health.
- You should also learn about other birth control methods to choose the one that is best for you.
- If you get any side effects, talk to your healthcare provider. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

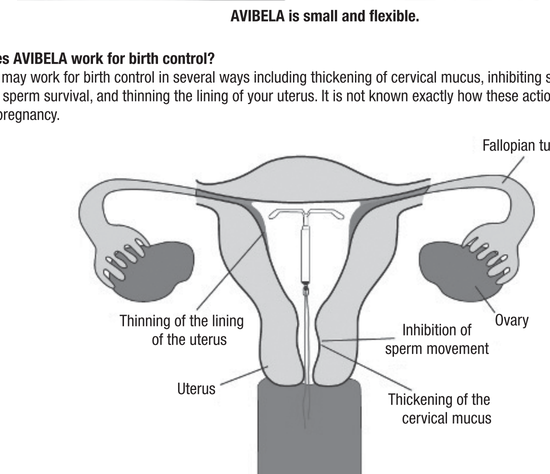
1. What AVIBELA is and what it is used for
- AVIBELA contains levonorgestrel and is a hormone-releasing system placed in your uterus by your healthcare provider to prevent pregnancy for up to 6 years
- AVIBELA can also be used to treat heavy menstrual bleeding (heavy periods)
- AVIBELA contains 52 mg of levonorgestrel, which is released slowly over 6 years
- AVIBELA can be removed by your healthcare provider at any time
- AVIBELA can be used whether or not you have given birth to a child.

AVIBELA is a small, flexible plastic T-shaped system that slowly releases a progestin hormone called levonorgestrel that is often used in birth control pills. Because AVIBELA releases levonorgestrel into your uterus, only small amounts of the hormone enter your blood. AVIBELA does not contain estrogen.
Two thin threads are attached to the stem (lower end) of AVIBELA. The threads are the only part of AVIBELA you can feel when AVIBELA is in your uterus; however, unlike a tampon string, the threads do not extend outside your body.



AVIBELA is small and flexible.

How does AVIBELA work for birth control?
AVIBELA may work for birth control in several ways including thickening of cervical mucus, inhibiting sperm movement, reducing sperm survival, and thinning the lining of your uterus. It is not known exactly how these actions work together to prevent pregnancy.



How does AVIBELA work for heavy menstrual bleeding?
The hormone in AVIBELA, levonorgestrel, acts by controlling the monthly development of the womb (uterus) lining, making it thinner, so that there is less bleeding every month.

2. What you need to know before AVIBELA is inserted
AVIBELA should not be inserted:
- if you are hypersensitive (allergic) to levonorgestrel or any of the other ingredients of AVIBELA (see section 6)
- if you are pregnant or suspect you are pregnant
- if you have an infection of your genitals
- if you have an infection of your female reproductive organs called pelvic inflammatory disease (PID) or you have any sexually transmitted disease (STDs) including the clap (bacterial infection also called gonorrhoea)
- if you have a painful disorder of the female reproductive organs called endometriosis, where the tissue which normally lines your uterus, grows outside your uterus, after giving birth
- if you had an abortion in the last three months, which was infected
- if you have inflammation of the cervix (the lower narrow end of the uterus that opens into the vagina) which includes symptoms like bleeding between menstrual periods, pain during sex or any abnormal vaginal discharge
- if you have inflammation of the vagina, which include symptoms like discharge, itching and pain in the vaginal area
- if you have abnormal growth of cells on the surface of your cervix or type of cervical cancer called neoplasm (as diagnosed by your doctor)
- if you have cancer of the uterus (womb)
- if you have a certain type of cancer which are hormone-sensitive, including breast cancer
- if you have abnormal bleeding from your womb, which have not been diagnosed
- if you have any abnormality of the uterus (womb) which can affect the insertion and/or holding of the intra-uterine device (IUD)
- if you have severe liver disease or liver cancer
- if you have another IUD which has not been removed
- if you have an illness that increases your likelihood to get infections
- if you have acute blood cancers, like leukaemia, unless you are in remission
- if you had recent abnormal cell growth in tissue that forms in the uterus (womb), while pregnancy hormone levels remain high.

Warnings and precautions
Tell your doctor or healthcare professional before insertion of the IUD if you:
- had a heart attack
- had a stroke
- were born with heart disease or have problems with your heart valves
- have problems with blood clotting or take medicine to reduce clotting
- have high blood pressure
- recently had a baby or if you are breastfeeding
- have severe migraine headaches or partial loss of vision associated with migraine headaches
- have severe or frequent headaches
- have AIDS, HIV, or any other sexually transmitted infection.

Special care should be taken with AVIBELA:
- if you develop blood clots with symptoms including pain in one leg and/or swelling, sudden severe pain in the chest which may extend to the left arm, sudden breathlessness, sudden onset of coughing, any unusual, severe, long-lasting headache, sudden partial or complete loss of eye sight, double-vision, slurred speech or struggling to communicate, sensation that the environment is moving or spinning, collapse with or without a fit, weakness or marked numbness suddenly affecting one side of or one part of the body, involuntary or uncontrollable movements or actions of the body, severe pain in abdomen caused by a condition called 'acute' abdomen
- if you develop blood clots in your eyes with symptoms like unexplained partial or complete loss of eyesight, bulging eyes or double vision, swelling of your optic nerve which may affect your vision or sudden change in eyesight due to a condition called retinal vascular lesions
- if you have been born with heart disease or have problems with your heart valves
- you may feel like fainting or experience lower than normal heart rate when the IUD is being inserted
- if you suffer from diabetes, your blood glucose levels should be monitored as AVIBELA may affect your glucose tolerance
- if you experience abnormal/changes in your period bleeding pattern, like spotting, irregular bleeding, heavy bleeding, infrequent menstrual periods, or absence of menstrual period. During the first 3 - 6 months of AVIBELA use, you may experience more than normal bleeding or spotting days and abnormal bleeding patterns may develop. Thereafter, the number of bleeding and spotting days may be less, but bleeding may still be irregular
- if you experience a heavier menstrual flow or unexplained bleeding, especially if you experience more cramping, it may indicate that AVIBELA has come out and you should be evaluated by your doctor
- if you develop lower abdominal pain or pain in your pelvis, fever, chill, unusual and smelly vaginal discharge, unexplained bleeding, sores on your genitals or experience pain during sex, notify your doctor immediately. You may have developed a condition called pelvic inflammatory disease
- if you had multiple sexual partners or your partner had multiple sex partners, you may be at risk to develop a sexually transmitted disease (STD). AVIBELA does not protect against STDs, and you may have a higher risk to develop the condition called pelvic inflammatory disease or inflammation of the womb. You may also have a higher risk to develop these conditions again, if you previously had any of these. Also, if you have blood cancer, AIDS or using illegal substances via injection, you may also have a higher risk to develop these conditions. These conditions may also be without any symptoms but can cause damage to your female reproductive organs
- if you develop a bacterial infection called actinomycosis. Symptoms include hard lump in the jaw that is not usually painful, muscle spasms or "locked jaw", draining sores in the skin, fever, mild or no pain, swelling or a hard, red to reddish-purple lump on the face or upper neck and weight loss
- AVIBELA may be expelled (come out) partially or completely, and may no longer be effective as birth control
- AVIBELA may perforate (pierce) your womb wall or cervix, mostly during insertion. If you experience severe pain and continued bleeding after insertion, please contact your doctor immediately, as delay in removal of AVIBELA may result in moving of the IUD outside your womb, adhesions (bands of scar like tissue), inflammation of the intestines, piercing/perforation of intestines, blockages in intestines, abscesses, and damage to the internal organs of the body
- if you have lower abdominal pain, in connection with missed periods or if your period starts and you did not have any periods while AVIBELA was inserted, you may have developed a pregnancy outside of your womb. You should contact your doctor immediately. This may affect your fertility
- you may develop cysts on your ovaries; however, they usually disappear in 2 - 3 months. Symptoms of ovarian cysts include pain in your pelvis, abdominal pain, and painful sex
- if you have breast cancer you should not use any form of hormonal birth-control, as some of the breast cancers are sensitive to these hormones.
- if you are a woman in menopause
- if you have a pigmentation disorder of the skin, called chloasma, in which large brown patches form on the skin. Avoid exposure to the sun or ultraviolet light.

Children and adolescents
AVIBELA should not be used before the first occurrence of menstruation and children below the age of 16 years.

Other medicines and AVIBELA
Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines)
- if you take any medicine which has an effect on the liver enzymes i.e.
  - primidone (used to treat seizures and shakiness)
  - barbiturates e.g. phenobarbitone (used to treat sleep disorders, anxiety, migraine)
  - phenytoin, carbamazepine, felbamate (used to treat epilepsy)
  - rifampicin (used to treat tuberculosis)
  - topiramate (used to treat epilepsy and migraines)
  - griseofulvin (used to treat fungus infections of nails, scalp, and skin)
  - rifabutin (used to prevent bacterial infections in patients with human immunodeficiency virus (HIV) infection
  - nevirapine (used to treat HIV) infection
  - efavirenz (used to treat HIV infection)
  - products containing St. John's wort.

Pregnancy, breastfeeding and fertility
AVIBELA should not be inserted if you are or suspect you are pregnant. If you suspect you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before AVIBELA is inserted. If possible, also do a urine pregnancy test. If you get pregnant while using AVIBELA, you may have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain especially with missed periods may be a sign of ectopic pregnancy.
Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death.

There are also risks if you get pregnant while using AVIBELA and the pregnancy is in the uterus. Severe infection, miscarriage, premature labour, premature delivery, and even death can occur with pregnancies that continue with an intrauterine device (IUD). Because of this, your healthcare provider may try to remove AVIBELA, even though removing it may cause a miscarriage. If AVIBELA cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy.

If you continue your pregnancy, see your healthcare provider regularly. Call your healthcare provider right away if you have flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection.

It is not known if AVIBELA can cause long-term effects on the foetus if it stays in place during a pregnancy.

Your healthcare provider can remove AVIBELA at any time. You could become pregnant as soon as AVIBELA is removed. About 6 out of 7 women who want to become pregnant will become pregnant sometime in the first year after AVIBELA is removed.

You may use AVIBELA when you are breastfeeding if more than 6 weeks have passed since you had your baby. If you are breastfeeding, AVIBELA is not likely to affect the quality or amount of your breast milk or the health of your nursing baby. However, isolated cases of decreased milk production have been reported among women using progestin-only birth control pills. You may have a higher risk that AVIBELA may attach to (embedded) or go through the walls of the womb (uterus) if you are breastfeeding. If you want to breastfeed your baby, you should ask a healthcare provider for advice on the risks and benefits while using AVIBELA.

Driving and using machines
It is not always possible to predict to what extent AVIBELA may interfere with your daily activities. There are no known effects on the ability to drive or use machines.

3. How AVIBELA is inserted
AVIBELA is inserted by your healthcare provider.
First, your healthcare provider will examine your pelvis to find the exact position of your uterus. Your healthcare provider will then clean your vagina and cervix with an antiseptic solution and slide a plastic tube containing AVIBELA through the cervix into your uterus. Your healthcare provider will then remove the plastic tube and leave AVIBELA in your uterus. Your healthcare provider will trim the threads to the right length.

You may experience pain, bleeding, or dizziness during and after placement. If your symptoms do not pass within 30 minutes after placement, AVIBELA may not have been placed correctly. Your healthcare provider will examine you to see if AVIBELA needs to be removed or replaced.

How soon after placement of AVIBELA should I return to my healthcare provider?
Call your healthcare provider if you have any questions or concerns. Otherwise, you should return to your healthcare provider for a follow-up visit 4 - 6 weeks after AVIBELA is placed to make sure that AVIBELA is in the right position.

After AVIBELA has been placed, when should I call my healthcare provider?
Call your healthcare provider if you have any concerns about AVIBELA. Be sure to call if you:
- think you are pregnant
- have pelvic pain or pain during sex
- have unusual vaginal discharge or genital sores
- have unexplained fever, flu-like symptoms, or chills
- might have been exposed to a sexually transmitted disease (STD)
- are concerned that AVIBELA may have been expelled (came out)
- cannot feel AVIBELA's threads
- develop very severe or migraine headaches
- have yellowing of the skin or whites of the eyes (these may be signs of liver problems)
- had a stroke or heart attack
- or your partner(s) become(s) HIV positive
- develop blood cancer (leukaemia)
- have severe vaginal bleeding, bleeding that lasts a long time, or you miss your period.

Should I check that AVIBELA is in place?
Yes, you should check that AVIBELA is in proper position by feeling the threads. It is a good habit to do this every month. Your healthcare provider should teach you how to check that AVIBELA is in place. First, wash your hands with soap and water. You can check by reaching up to the top of your vagina with clean fingers to feel the threads. Do not pull on the threads.
If you feel more than just the threads or if you cannot feel the threads, AVIBELA may not be in the right position and may not prevent pregnancy. Use non-hormonal back-up birth control (such as condoms and spermicide) and ask your healthcare provider to check that AVIBELA is still in the right place.

How will AVIBELA change my periods?
For the first 3 - 6 months, your period may become irregular, and the number of bleeding days may increase. You may also have frequent spotting or light bleeding and cramping. Some women have heavy bleeding during this time. After you have used AVIBELA for a while, the number of bleeding and spotting days is likely to lessen. For some women, menstrual periods will stop altogether. When AVIBELA is removed, your menstrual periods will likely return to their former pattern.

Will AVIBELA interfere with sexual intercourse?
You and your partner should not feel AVIBELA during intercourse. AVIBELA is placed in the uterus, not in the vagina. In some cases, your partner may feel the threads. If this occurs, or if you or your partner experience pain during sex, talk with your healthcare provider.

What if I want to stop using AVIBELA?
AVIBELA is intended for use up to 6 years for contraception, but you can stop using AVIBELA at any time by asking your healthcare provider to remove it. You could become pregnant as soon as AVIBELA is removed, so you should use another method of birth control if you do not want to become pregnant. Talk to your healthcare provider about the best birth control methods for you, because your method may need to be started 7 days before AVIBELA is removed to prevent pregnancy.

4. Possible side effects
AVIBELA can have side effects.
Not all side effects reported for AVIBELA are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using AVIBELA, please consult your doctor, pharmacist or other healthcare professional for advice.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- **ectopic pregnancy:** If you get pregnant while using AVIBELA, you might have an ectopic pregnancy. This means that the pregnancy is not in the uterus. Unusual vaginal bleeding or abdominal pain especially with missed periods may be a sign of ectopic pregnancy. Ectopic pregnancy is a medical emergency that often requires surgery. Ectopic pregnancy can cause internal bleeding, infertility, and even death
- **intrauterine pregnancy risks:** There are also risks if you get pregnant while using AVIBELA and the pregnancy is in the uterus. Severe infection, miscarriage, premature labour, premature delivery, and even death can occur with pregnancies that continue with an intrauterine system (IUD). Because of this, your healthcare provider may try to remove AVIBELA, even though removing it may cause a miscarriage. If AVIBELA cannot be removed, talk with your healthcare provider about the benefits and risks of continuing the pregnancy. If, after seeing your healthcare provider, you choose to continue your pregnancy, see your healthcare provider regularly. Call your healthcare provider right away if you get flu-like symptoms, fever, chills, cramping, pain, bleeding, vaginal discharge, or fluid leaking from your vagina. These may be signs of infection. It is not known if AVIBELA can cause long-term effects on the foetus if it stays in place during a pregnancy
- **life-threatening infection:** Life-threatening infection can occur within the first few days after AVIBELA is placed. Call your healthcare provider immediately if you develop severe pain or fever shortly after AVIBELA is placed
- **pelvic inflammatory disease (PID) or endometritis:** Some IUD users get a serious pelvic infection called pelvic inflammatory disease (PID) or endometritis. PID and endometritis are usually sexually transmitted. You have a higher chance of getting PID or endometritis if you or your partner has sex with other partners. PID or endometritis can cause serious problems such as infertility, ectopic pregnancy, or pelvic pain that does not go away. PID is usually treated with antibiotics. More serious cases of PID or endometritis may require surgery. Removal of the uterus (hysterectomy) is sometimes needed. In rare cases, infections that start as PID or endometritis can even cause death.

Tell your healthcare provider right away if you have any of these signs of PID or endometritis: long-lasting or heavy bleeding, unusual vaginal discharge, low abdominal pain, painful sex, chills, or fever
- **perforation:** AVIBELA may partially go into the wall of the uterus (become embedded) or go completely through the wall of the uterus (perforate). If this occurs, AVIBELA may no longer prevent pregnancy. If perforation occurs, AVIBELA may move outside the uterus and can cause internal scarring, infection, or damage to other organs. You may need surgery to have AVIBELA removed if it is embedded, or perforation occurs. The risk of perforation is increased in breastfeeding women
- **expulsion:** AVIBELA may come out of your uterus (expulsion). Expulsion occurs in about 4 out of 100 women, most often in the first year of use. You may become pregnant if AVIBELA comes out. If you think that AVIBELA has come out, use another birth control method like condoms and spermicide or do not have sex (vaginal intercourse) until you are seen by a healthcare provider
- **cysts on the ovary:** Some women using AVIBELA develop a painful cyst on the ovary. These cysts usually disappear on their own in 2 - 3 months. However, a cyst can cause pain and sometimes cysts will need surgery
- **changes in bleeding:** You may have bleeding and spotting between menstrual periods, especially during the first 3 - 6 months. Sometimes the bleeding is heavier than usual at first. However, the bleeding usually becomes lighter than usual and may be irregular. Call your healthcare provider if the bleeding remains heavier than usual or increases after it has been light for a while.

These are all serious side effects. You may need urgent medical attention.

Very common and common side effects of AVIBELA include:
- vaginal infection caused by bacteria, yeast infection of the outer part of your vagina (vulvovaginal)
- anxiety, depression, mood changes, sleeplessness, lower sex drive
- headache, migraine (a severe headache, often accompanied by nausea and sensitivity to light and sound), near fainting, dizziness, fainting
- nausea, pain/discomfort in your abdomen, bloating and swelling in the belly area, constipation, indigestion, diarrhoea, vomiting
- acne (pimples), hair loss
- back pain, pain in legs or arms
- severe and frequent menstrual cramps and pain during your period, pain during sex, breast pain/tenderness, pain/discomfort in your pelvis, spasm of your womb (uterus), discharge from your vagina, dryness/discomfort of your vagina and genital area, menstrual bleeding that lasts more than 7 days, bleeding after having sex (not related to your period), funny odour from your vagina, any vaginal/womb bleeding unrelated to your normal period, including spotting, infrequent menstrual periods, heavy menstrual bleeding
- weight gain, abnormal ovaries as detected by ultrasound
- bleeding after device has been inserted, device is expelled (ejected), pain during the procedure of inserting the device, device moved from where it was placed.

Uncommon and rare side effects include:
- worsening of a mental disorder called bipolar disorder (episodes of mood swings, ranging from depressive lows to manic highs), feeling suicidal
- excessive hair growth of dark coarse hair in a male-like pattern, i.e. around mouth, chin, face, chest and back
- greasy hair
- infection of the connective tissue next to your womb, infection of the fallopian tubes or other parts of the female reproductive organs, menstrual cycle is shorter than 21 days
- swelling of the abdomen and swelling of the hands and feet.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Pain, bleeding, or dizziness during and after insertion. If these symptoms do not stop within 30 minutes after insertion, AVIBELA may not have been placed correctly, or these may be symptoms of perforation or expulsion. Your healthcare provider should examine you to see if AVIBELA needs to be removed or replaced.

Missed menstrual periods. About 2 out of 10 women stop having periods after 1 year of AVIBELA use. If you do not have a period for 6 weeks during AVIBELA use, call your healthcare provider. If you have any concerns that you may be pregnant while using AVIBELA, do a urine pregnancy test and call your healthcare provider. When AVIBELA is removed, your menstrual periods will usually return to their previous pattern.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of AVIBELA.
You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store AVIBELA
Store all medicines out of reach of children.
Store at or below 30 °C.
Store in the original package. Keep the sealed tray in the outer carton in order to protect from light. Do not open the AVIBELA pack. Only your healthcare provider should do this.
Do not use after the expiry date stated on the label and the outer pack after expiry date. The expiry date refers to the last day of that month.

6. Contents of the pack and other information
What AVIBELA contains:
AVIBELA contains 52 mg of levonorgestrel, the active substance.
The hormone is contained within a substance called polydimethylsiloxane. This is surrounded by a membrane (skin) also made of polydimethylsiloxane.

The other ingredients are:
Reservoir of the IUD
Silicone base, stannous octoate, tetra-n-propyl silicate.

T-frame
Low density polyethylene (LDPE), barium sulphate, polydimethylsiloxane (PDMS) membrane, polypropylene thread dyed with phthalocyaninato (2-) copper.

What AVIBELA looks like and contents of the pack
AVIBELA consists of a small T-shaped frame made from a plastic called polyethylene. This structure provides a device for releasing the hormone gradually into the uterus (womb). There are two fine blue threads, made of polypropylene and copper phthalocyanine blue, attached to the bottom of the T-frame. These allow easy removal and allow you or your healthcare provider to check that AVIBELA is in place.

AVIBELA with the inserter device is supplied partially preloaded within the inserter and packaged in a clear plastic tray with lid. AVIBELA is available in a carton of one sterile unit.

Holder of Certificate of Registration

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PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S4

AVIBELA 20 mikrogram/24 uur intrauteriene afleweringstelsel
Levonorgestrel
Suikervry

AVIBELA beskerm nie teen mens-immuungebrekvirus (MIV) infeksie of verworwe immuungebreksindroom (VIGS) en ander seksueel oordraagbare siektes (SOS) nie.

Lees hierdie hele inligtingsblad deeglik deur, voordat u 'n AVIBELA inplasing ontvang
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter, of apteker. Hierdie inligting vervang nie u gesprek met u ginekoloog, of ander gesondheidsorgverskaffer wat spesialiseer in vrouegesondheid, nie.
- U moet ook kennis dra van ander geboortebeperkingsmetodes, om op die gepaste opsie vir u te besluit.
- Indien u enige newe-effekte ervaar, praat met u gesondheidsorgverskaffer. Dit sluit enige moontlike newe-effekte in wat nie in hierdie inligtingsblad gelys word nie. Sien afdeling 4.

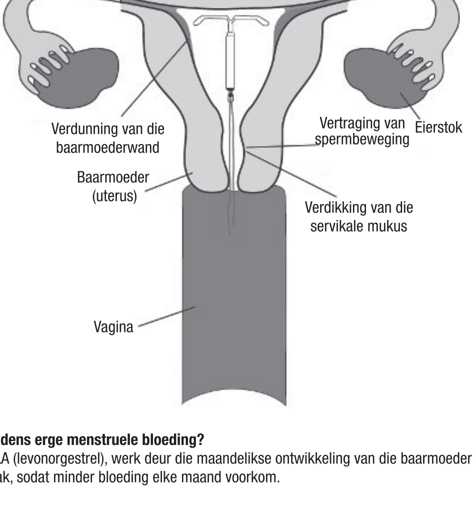
Inhoud van hierdie inligtingsblad

1. Wat AVIBELA is en waarvoor dit gebruik word
- AVIBELA bevat levonorgestrel en is 'n hormoonvrystellingstoestel wat in u uterus, deur u gesondheidsorgverskaffer geplaas word, om swangerskap vir tot en met 6 jaar, te verhoed.
- AVIBELA kan ook gebruik word om erge menstruele bloeding (erge menstruasie), te behandel.
- AVIBELA bevat 52 mg levonorgestrel, wat stadig, oor 'n tydperk van 6 jaar, vrygestel word.
- AVIBELA kan deur u gesondheidsorgverskaffer op enige tydstip, verwyder word.
- AVIBELA kan gebruik word, of u geboorte geskenk het aan 'n kind, of nie.

AVIBELA is 'n klein, buigbare, T-vormige toestel, wat 'n progestien-hormoon wat levonorgestrel genoem word en dikwels in geboortebeperkingstablette gebruik word, stadig vrystel. Slegs klein hoeveelhede van die hormoon kom in u bloed voor, omdat AVIBELA levonorgestrel in u uterus vrystel. AVIBELA bevat geen estrogeen nie.
Twee dun draadjies is aan die stingel (onderste gedeelte) van AVIBELA vasgeheg. Hierdie draadjies, is die enigste gedeelte van AVIBELA wat u kan voel, wanneer AVIBELA in u uterus geplaas is; anders as 'n tampon-toutjie, hang die draadjies egter nie by u liggaam uit nie.

AVIBELA is klein en buigbaar.

Hoe werk AVIBELA vir geboortebeperking?
AVIBELA mag op verskeie wyses vir geboortebeperking werk, insluitend verdikking van die servikale mukus, vertraging van spermbeweging, vermindering van spermoorlewing en verdunning van die baarmoederwand. Dit is onbekend hoe hierdie werkswyses saamwerk om swangerskap te verhoed.



Hoe AVIBELA werk tydens erge menstruele bloeding?
Die hormoon in AVIBELA (levonorgestrel), werk deur die maandelikse ontwikkeling van die baarmoeder (uterus) wand te beheer, deur dit dunner te maak, sodat minder bloeding elke maand voorkom.

2. Wat u nodig het om te weet, voordat AVIBELA vir u ingeplaas word
AVIBELA moet nie ingeplaas word:
- indien u hipersensitief (allergies) is vir levonorgestrel, of enige van die ander bestanddele van AVIBELA nie (sien afdeling 6)
- indien u swanger is, of vermoed dat u swanger is nie
- indien u 'n infeksie van u geslagsdele het nie
- indien u 'n infeksie van u vroulike voortplantingsorgane, wat pelviese inflammatoriese siekte (PIS) genoem word, of u enige seksueel oordraagbare siekte (SOS), insluitend druiper (bakteriële infeksie wat ook gonorree genoem word) het nie
- indien u 'n pynlike versteuring van die van die vroulike voortplantingsorgane, wat endometriose genoem word het, waar die weefsel wat gewoonlik die uterus uitvoer, aan die buitekant van die uterus groei nadat u geboorte geskenk het nie
- indien u 'n aborsie wat besmet geraak het, tydens die laaste drie maande gehad het nie
- indien u inflammasie van die serviks (die onderste gedeelte van die uterus wat in die vagina open), en simptome soos bloeding tussen menstruele siklusse, pyn tydens seks, of enige abnormale vaginale afskeiding ondervind nie
- indien u inflammasie van die vagina, wat simptome soos afskeiding, gejeuk en pyn in die vaginale omgewing insluit, ondervind nie
- indien u abnormale selgroei op die oppervlakte van die serviks, soos gediagnoseer deur u dokter, ('n tipe servikale kanker wat neoplasma genoem word), het nie
- indien u kanker van die uterus (baarmoeder) het nie
- indien u 'n sekere tipe kanker, wat hormoon-sensitief is, insluitend borskanker, het nie
- indien u abnormale bloeding vanuit u baarmoeder ondervind, wat nog nie gediagnoseer is nie
- indien u enige abnormaliteit van die uterus (baarmoeder) ondervind, wat die inplasing en/of vashegting van die intrauteriene toestel (IUT) kan beïnvloed nie
- indien u erge lewersiekte of lewerkanker het nie
- indien u 'n ander IUT wat nog nie verwyder is, het nie
- indien u 'n siekte, wat die moontlikheid vir infeksies vir u verhoog, het nie
- indien u akute bloedkankers soos leukemie het nie, tensy u in remissie is
- indien u onlangs abnormale weefselgroei in die uterus (baarmoeder) gehad het, terwyl swangerskaphormoonvlakke hoog was.

Waarskuwings en voorsorgmaatreëls
Vertel u dokter of gesondheidsorgverskaffer, voordat die IUT vir u ingeplaas word, indien u:
- 'n hartaanval gehad het
- 'n beroerte gehad het
- gebore was met 'n hartsiekte, of probleme met u hartkleppe ondervind
- probleme met bloedstolling het, of medisyne neem om bloedstolling te verminder
- hoë bloeddruk het
- onlangs 'n baba gehad het, of indien u borsvoed
- erge migraine hoofpyne ervaar, of gedeeltelike sigverlies wat gepaardgaan met migraine hoofpyne, ondervind
- erge of gereelde hoofpyne ervaar
- VIGS, MIV, of enige ander seksueel oordraagbare infeksie het.

Spesiale sorg moet met AVIBELA geneem word:
- indien u bloedklonte ontwikkel, met simptome wat pyn in een been en/of swelling, skielike pyn in die bors, wat mag uitstraal na die linkerarm, skielike asemnood, skielike hoes, enige ongewone erge en langdurige hoofpyn, skielike gedeeltelike of algehele sigverlies, dubbelvisie, slepende spraak, of probleme om te kommunikeer, sensasie dat die die omgewing beweeg of draai, ineenstorting met of sonder stuipe, swakheid of opmerklike gevoelloosheid wat skielik die een kant of een gedeelte van die liggaam aantas, onwillekeurige of onbeheerbare bewegings of aksies van die liggaam, erge buikpyn wat veroorsaak word deur 'n toestand wat "akute" abdomen genoem word, insluit
- indien u bloedklonte in u oë ontwikkel, met simptome soos onverklaarbare gedeeltelike of algehele sigverlies, bultende oë, of dubbelvisie, swelling van u optiese senuwee, wat u sig mag aantas, of skielike verandering in sig weens 'n toestand wat retinale vaskulêre letsels, genoem word
- indien u gebore is met 'n hartsiekte, of probleme met u hartkleppe het
- u mag voel asof u wil flou word, of 'n laer as normale hartklop ervaar, wanneer die IUT ingeplaas word
- indien u aan diabetes ly, moet u bloedglukosevlakke gemonitor word, aangesien AVIBELA u glukoseverdraagsaamheid mag beïnvloed
- indien u abnormale/veranderinge in u menstruele bloedingspatroon, soos vlekking, ongereelde bloeding, erge bloeding, wisselvallige menstruele siklusse, of die afwesigheid van menstruasie, ervaar. Tydens die eerste 3 - 6 maande van AVIBELA gebruik, mag u meer as normale bloedings- of vlekkingsdae ervaar en abnormale bloedingspatrone mag ontwikkel. Daarna, mag die bloedings- en vlekkingsdae afneem, maar bloeding mag steeds wisselvallig wees
- indien u erger menstruele vloei, of onverklaarbare bloeding ondervind, veral indien dit gepaardgaan met meer krampe, mag dit 'n aanduiding wees dat AVIBELA verwyder moet word en u deur u dokter ondersoek moet word
- indien u onderste buikpyn, of pyn in u pelvis, koors, koue rillings, ongewone en onwelriekende vaginale afskeiding, onverklaarbare bloeding, sere op u geslagsdele, of pyn tydens geslagsgemeenskap ervaar, raadpleeg u dokter onmiddellik. U mag 'n toestand, wat pelviese inflammatoriese siekte genoem word, ondervind
- indien u of u metgesel, veelvuldige seksmaats gehad het, mag u 'n risiko toon om 'n seksueel oordraagbare siekte (SOS), te ontwikkel. AVIBELA beskerm nie teen SOS nie en u mag 'n hoër risiko toon om die toestand, wat pelviese inflammatoriese siekte genoem word, of inflammasie van die baarmoeder, te ontwikkel. U mag ook 'n hoër risiko toon, om hierdie toestande weer te ontwikkel, indien u dit voorheen gehad het. Ook, indien u bloedkanker of VIGS het, of onwettige middels via inspuiting gebruik, mag u ook 'n hoër risiko om hierdie toestande te ontwikkel, toon. Hierdie toestande mag ook sonder enige simptome voorkom, maar kan skade aan u vroulike voortplantingsorgane berokken
- indien u 'n bakteriële infeksie wat aktinomikose genoem word, ontwikkel. Simptome sluit 'n harde knop in die kakebeen, wat gewoonlik nie pynlik is nie, spierspasmas of "trismus", dreinerende sere op die vel, koors, ligte, of geen pyn, swelling of 'n harde, rooi, tot rooi-pers knop op die gesig of boonste gedeelte van die nek en gewigsverlies, in
- AVIBELA mag gedeeltelik of volkome uitgewerp word (uitkom) en mag nie langer doeltreffend as geboortebeperking wees nie
- AVIBELA mag u baarmoeder- of serviksand, meestal tydens inplasing, perforeer (deurboor). Indien u erge pyn en voortdurende bloeding na inplasing ervaar, kontak asseblief u dokter onmiddellik, aangesien vertraging in die verwydering van AVIBELA mag lei tot die beweging van die IUT na die buitekant van die baarmoeder, vashegting (stroke litteken-tipe weefsel), inflammasie van die derms, deurboring/perforasie van die derms, blokkade in die derms, absesse en skade aan die interne organe van die liggaam
- indien u onderste buikpyn, wat verband hou met menstruasie wat oorgeslaan is, of u menstruasie wat begin en u geen menstruasie ervaar het terwyl AVIBELA ingeplaas was nie, is dit moontlik dat u 'n swangerskap aan die buitekant van die baarmoeder ontwikkel het. U moet u dokter onmiddellik kontak. Dit mag u fertiliteit aantas
- u mag siste op u eierstokke ontwikkel, dit verdwyn egter gewoonlik na 2 - 3 maande. Simptome van ovariale siste sluit bekkenpyn, buikpyn en pynlike seks in
- indien u borskanker het, moet u nie enige vorm van hormonale geboortebeperking gebruik nie, aangesien sommige borskankers, sensitief is vir hierdie hormone
- indien u 'n vrou is tydens menopouse
- indien u 'n pigmentasieversteuring van die vel het, wat chloasma genoem word, waar groot bruin vlekke op die vel vorm. Vermy blootstelling aan die son, of ultraviolet lig.

Kinders en adolessente
AVIBELA moet nie gebruik word, voor die eerste voorkoms van menstruasie en deur kinders jonger as 16 jaar oud nie.

Ander medisyne en AVIBELA
Vertel altyd u gesondheidsorgverskaffer indien u enige ander medisyne neem (Dit sluit aanvullende, of tradisionele medisyne in).
- indien u enige medisyne neem wat 'n uitwerking op die lewerensieme het d.i.
  - primidoon (gebruik om aanvalle en beweerigheid te behandel)
  - barbiturate bv. fenobarbitoon (gebruik om slaapversteurings, angstigheid, migraine te behandel)
  - fenitoïen, karbamasepien, felbamaat (gebruik om epilepsie te behandel)
  - rifampisien (gebruik om tuberkulose te behandel)
  - topiramaat (gebruik om epilepsie en migraines te behandel)
  - griseofulvien (gebruik om swaminfeksies van die naels, kopvel en vel te behandel)
  - rifabutien (gebruik om bakteriële infeksies by pasiënte met mens-immuungebrekvirus (MIV) infeksie te verhoed
  - nevirapien (gebruik om MIV-infeksie te behandel)
  - efavirens (gebruik om MIV-infeksie te behandel)
  - middels wat Johanneskruid bevat.

Swangerskap, borsvoeding en fertiliteit
AVIBELA moet nie ingeplaas word, indien u swanger is, of vermoed dat u swanger is nie. Indien u swangerskap vermoed, of u baba borsvoed, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer vir advies, voordat AVIBELA ingeplaas word. Indien moontlik, voer ook 'n urien-swangerskaptoets uit. Indien u swanger raak, terwyl u AVIBELA gebruik, kon u 'n ektopiese swangerskap ontwikkel het. Dit beteken, dat die swangerskap nie in die uterus ontwikkel het nie. Ongewone vaginale bloeding, of buikpyn (veral saam met menstruele siklusse wat oorgeslaan was), mag 'n teken van ektopiese swangerskap wees.
Ektopiese swangerskap, is 'n mediese noodgeval, wat dikwels 'n operasie verg. Ektopiese swangerskap kan interne bloeding, infertiliteit en selfs die dood, veroorsaak.

Daar is ook risiko's indien u sou swanger raak, terwyl u AVIBELA gebruik en die swangerskap vind in die uterus plaas. Erge infeksie, miskraam voortydige geboorte en selfs die dood mag voorkom tydens swangerskappe wat voortduur met 'n intrauteriene toestel (IUT). As gevolg hiervan, mag u gesondheidsorgverskaffer probeer om AVIBELA te verwyder, selfs al veroorsaak die verwydering, 'n miskraam. Indien AVIBELA nie verwyder kan word nie, praat met u gesondheidsorgverskaffer omtrent die voordele en risiko's om met die swangerskap voort te gaan.

Indien u voortgaan met die swangerskap, besoek u gesondheidsorgverskaffer gereeld. Kontak u gesondheidsorgverskaffer onmiddellik indien u griep-soortige simptome, koors, koue rillings, krampe, pyn, bloeding, vaginale afskeiding, of vloeistof wat vanuit u vagina lek, ondervind. Hierdie mag tekens van infeksie wees.

Dit is onbekend of AVIBELA langtermyn effekte op die fetus kan veroorsaak, indien dit nie verwyder word tydens swangerskap nie.

U gesondheidsorgverskaffer kan AVIBELA op enige tydstip verwyder. U kan swanger raak, sodra AVIBELA verwyder is. Omtrent 6 uit 7 vroue wie swanger wil raak, word swanger iewers tydens die eerste jaar nadat AVIBELA verwyder is.

U mag AVIBELA gebruik wanneer u borsvoed, indien meer as 6 weke verstryk het, vandat u geboorte geskenk het aan u baba. Dit is onwaarskynlik dat AVIBELA u kwaliteit of hoeveelheid borsmelk beïnvloed, of die gesondheid van u borsvoedende baba aantas, indien u sou borsvoed. Daar is egter geïsoleerde gevalle waar 'n afname in melkproduksie aangemeld is by vroue wie progestien-alleen geboortebeperkingstablette gebruik. U mag 'n hoër risiko toon dat AVIBELA kan vasheg (anker), of die wand van baarmoeder (uterus) penetreer, indien u sou borsvoed. U moet 'n gesondheidsorgverskaffer vra vir advies aangaande die risiko's en voordele, indien u u baba wil borsvoed terwyl u AVIBELA gebruik.

Bestuur en die hantering van masjiene
Dit is nie altyd moontlik om te voorspel tot watter mate AVIBELA met u daaglikse aktiwiteite sal inmeng nie. Daar is geen bekende effekte op die vermoë om te bestuur of masjiene te hanteer nie.

3. Hoe Avibela ingeplaas word
AVIBELA word deur u gesondheidsorgverskaffer ingeplaas.
Eerstens sal u gesondheidsorgverskaffer u bekken ondersoek, om die presiese posisie van u uterus te bepaal. U gesondheidsorgverskaffer sal dan u vagina en serviks met 'n antiseptiese oplossing skoonmaak en 'n plastiekbuis, wat AVIBELA bevat, deur die serviks, in die uterus ingly. U gesondheidsorgverskaffer sal dan die plastiekbuis verwyder en AVIBELA in u uterus agterlaat. U gesondheidsorgverskaffer sal die draadjies knip tot die gepaste lengte.

U mag pyn, bloeding, of duiseligheid tydens, en na inplasing ondervind. Indien u simptome nie na 30 minute vandat dit ingeplaas is verdwyn nie, is dit moontlik dat AVIBELA nie korrek ingeplaas is nie. U gesondheidsorgverskaffer sal u ondersoek om vas te stel of AVIBELA verwyder, of vervang moet word.

Hoe gou na die inplasing van AVIBELA moet ek na my gesondheidsorgverskaffer terugkeer?
Skakel u gesondheidsorgverskaffer indien u enige vrae of bekommernisse het. Anders moet u na 4 - 6 weke vandat AVIBELA ingeplaas is vir 'n opvolgondersoek na u gesondheidsorgverskaffer terugkeer, om seker te maak dat AVIBELA in die regte posisie is.

Wanneer moet ek my gesondheidsorgverskaffer kontak, na die inplasing van Avibela?
Skakel u gesondheidsorgverskaffer indien u enige bekommernisse het oor AVIBELA. U moet veral kontak maak indien u:
- vermoed dat u swanger is
- bekkenpyn, of pyn tydens seks ervaar
- ongewone vaginale afskeiding of genitale sere opmerk
- onverklaarbare koors, griep-soortige simptome, of koue rillings ervaar
- blootgestel kon gewees het aan 'n seksueel oordraagbare siekte (SOS)
- bekommerd is dat AVIBELA uitgewerp (uitgekom het) mag wees
- nie AVIBELA se draadjies voel nie
- baie erge migraine hoofpyne ontwikkel
- vergeling van die vel, of wit gedeeltes van die oë ondervind (hierdie mag tekens van lewerprobleme wees)
- 'n beroerte of hartaanval gehad het
- of u metgesel (le) MIV-positief word
- bloedkanker (leukemie) ontwikkel
- erge vaginale bloeding of langdurige bloeding ervaar, of indien u 'n menstruasie oorslaan.

Moet ek seker maak dat AVIBELA in plek is?
Ja, u moet seker maak dat AVIBELA in 'n behoorlike posisie is, deur die draadjies te voel. Dit is 'n goeie gewoonte om dit elke maand te doen. U gesondheidsorgverskaffer moet u leer hoe om seker te maak dat AVIBELA behoorlik in plek is. Was eers u hande met seep en water. U kan seker maak, deur met skoon vingers, die draadjies aan die bokant van die vagina te voel. Moet nie aan die draadjies trek nie. Indien u meer as net die draadjies voel, of u voel glad nie die draadjies nie, mag dit wees dat AVIBELA nie in die regte posisie is en nie swangerskap mag verhoed nie. Gebruik nie-hormonale bykomende geboortebeperking (soos kondome en spermdoder) en vra u gesondheidsorgverskaffer om seker te maak dat AVIBELA steeds in die regte posisie is.

Hoe sal AVIBELA my menstruasie verander?
Vir die eerste 3 - 6 maande, mag u menstruasiepatroon onreëlmatig voorkom en die hoeveelheid bloedingsdae, mag toeneem. U mag ook gereelde vlekking, of ligte bloeding en krampe ervaar. Sommige vroue ervaar erge bloeding tydens hierdie tydperk. Nadat u AVIBELA vir 'n wyle gebruik het, is dit waarskynlik dat die hoeveelheid bloedings- en vlekkingsdae sal verminder. By sommige vroue is die menstruele siklusse totaal afwesig. U menstruele siklusse sal heel waarskynlik na die gewone patroon terugkeer, wanneer AVIBELA verwyder word.

Sal AVIBELA inmeng met seksuele omgang?
U en u metgesel sal nie AVIBELA tydens geslagsgemeenskap voel nie. AVIBELA word in die uterus geplaas, nie in die vagina nie. In sommige gevalle, mag u metgesel die draadjies voel. Indien dit sou voorkom, of indien u of u metgesel pyn tydens seks ervaar, praat met u gesondheidsorgverskaffer.

Wat gebeur as ek die gebruik van AVIBELA wil staak?
AVIBELA word aangedui vir gebruik vir geboortebeperking, tot en met 6 jaar, maar u kan die gebruik van AVIBELA op enige tydstip staak, deur u gesondheidsorgverskaffer te vra om dit te verwyder. U mag swanger raak so gou as wat AVIBELA verwyder is, daarom moet u 'n ander metode van geboortebeperking toepas indien u nie wil swanger raak nie. Praat met u gesondheidsorgverskaffer omtrent die mees gepaste geboortebeperkingsmetodes vir u, aangesien dit nodig mag wees om u eie metode, 7 dae voordat AVIBELA verwyder word, te begin gebruik om swangerskap te verhoed.

4. Moontlike newe-effekte
AVIBELA kan newe-effekte hê.
Nie alle newe-effekte wat vir AVIBELA aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid versleg, of indien u enige ongunstige effekte ervaar terwyl u AVIBELA gebruik, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgdeskundige vir advies.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- **ektopiese swangerskap:** Indien u swanger raak, terwyl u AVIBELA gebruik, het u moontlik 'n ektopiese swangerskap. Dit beteken dat die swangerskap nie in die uterus voorkom nie. Ongewone vaginale bloeding, of buikpyn, veral gepaardgaande met menstruasiesiklusse wat oorgeslaan word, mag 'n teken van ektopiese swangerskap wees. Ektopiese swangerskap is 'n mediese noodgeval wat dikwels 'n operasie vereis. Ektopiese swangerskap kan interne bloeding, infertiliteit en selfs die dood veroorsaak
- **intrauteriene swangerskap risiko's:** Daar is ook risiko's indien u swanger raak terwyl u AVIBELA gebruik en die swangerskap kom in die uterus voor. Erge infeksie, miskraam, vroegtydige kraam, vroegtydige geboorte en selfs die dood mag voorkom tydens swangerskappe en die voortdurende gebruik van 'n intrauteriene toestel (IUT). As gevolg hiervan, mag u gesondheidsorgverskaffer probeer om AVIBELA te verwyder, selfs al mag die verwydering tot 'n miskraam lei. Indien AVIBELA nie verwyder kan word nie, praat met u gesondheidsorgverskaffer omtrent die voordele en risiko's om met die swangerskap voort te gaan. Indien u na die gesprek met die gesondheidsorgverskaffer sou besluit om met die swangerskap voort te gaan, besoek u gesondheidsorgverskaffer gereeld. Skakel u gesondheidsorgverskaffer onmiddellik indien u griep-soortige simptome, koors, koue rillings, krampe, pyn, bloeding, vaginale afskeiding, of vloeistof wat vanuit u vagina lek, ervaar. Dit mag tekens van infeksie wees. Dit is onbekend of AVIBELA langtermyn effekte op die fetus kan veroorsaak, indien dit in posisie bly tydens 'n swangerskap
- **lewensbedreigende infeksie:** Lewensbedreigende infeksie mag voorkom binne etlike dae nadat AVIBELA ingeplaas is. Skakel u gesondheidsorgverskaffer onmiddellik, indien u erge pyn of koors ontwikkel, kort nadat AVIBELA ingeplaas is
- **pelviese inflammatoriese siekte (PIS) of endometritis:** Sommige IUT-gebruikers ontwikkel 'n ernstige bekkeninfeksie wat pelviese inflammatoriese siekte (PIS), of endometritis genoem word en is gewoonlik seksueel oorgedra. U het 'n groter moontlikheid om PIS of endometritis te ontwikkel indien u of u metgesel, seks met ander metgeselle gehad het. PIS of endometritis kan ernstige probleme soos infertiliteit, ektopiese swangerskap, of blywende bekkenpyn veroorsaak. PIS word gewoonlik behandel met antibiotika. Meer ernstige gevalle van PIS of endometritis mag 'n operasie vereis. Somtyds word die verwydering van die uterus (histerektomie) benodig. In skaars gevalle kan infeksies wat begin as PIS of endometritis, selfs noodlottig wees.

Vertel u gesondheidsorgverskaffer onmiddellik, indien u enige van hierdie tekens van PIS of endometritis toon: langdurige of erge bloeding, ongewone vaginale afskeiding, lae buikpyn, pynlike seks, koue rillings, of koors
- **perforasie:** AVIBELA mag die uteruswand gedeeltelik penetreer (vasheg daaraan). Indien dit voorkom, verhoed AVIBELA nie langer swangerskap nie. Indien perforasie voorkom, kan AVIBELA na die buitekant van die uterus beweeg en interne littekens, infeksie, of skade aan ander organe veroorsaak. U mag 'n operasie benodig om AVIBELA te verwyder indien dit vasgeheg is, of perforasie voorkom. Die risiko vir perforasie neem toe by lakterende vroue
- **uitwerping:** AVIBELA mag uit die uterus beweeg (uitwerping). Uitwerping kom voor by omtrent 4 uit elke 100 vroue, meestal tydens die eerste jaar van gebruik. U mag swanger raak, indien AVIBELA uitkom. Indien u vermoed dat AVIBELA uitgekom het, gebruik 'n ander vorm van geboortebeperking soos kondome en spermdoder, of weerhou seks (vaginale geslagsgemeenskap), totdat u deur u gesondheidsorgverskaffer gesien is
- **siste op die eierstok:** Sommige vroue wie AVIBELA gebruik, ontwikkel 'n pynlike sist op die eierstok. Hierdie siste verdwyn gewoonlik vanself binne 2 - 3 maande. 'n Sist kan egter pyn veroorsaak, en verg somtyds 'n operasie
- **bloedingsveranderinge:** U mag bloeding en vlekking tussen menstruele siklusse ervaar, veral tydens die eerste 3 - 6 maande. Somtyds is die bloeding erger as gewoonlik aan die begin. Die bloeding word egter minder as gewoonlik en mag ongereeld wees. Skakel u gesondheidsorgverskaffer indien die bloeding erger as gewoonlik voortduur, of toeneem, nadat dit lig was vir 'n wyle.

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Baie algemene en algemene newe-effekte van AVIBELA sluit die volgende in:
- vaginale infeksie veroorsaak deur bakterieë, gisinfeksie van die buitenste gedeelte van u vagina (vulvo-vaginaal)
- angstigheid, depressie, gemoedsveranderinge, slaaploosheid, laer seksdrang
- hoofpyn, migraine ('n erge hoofpyn, dikwels gepaardgaande met naarheid en sensitiwiteit vir lig en klank), word amper flou, duiseligheid, floute
- naarheid, pyn/ongemak in u buik, opgeblase en geswel in die maagarea, hardlywigheid, indigestie, diarree, braking
- aknee (puisies), haarverlies
- rugpyn, pyn in die bene of arms
- erge en gereelde menstruele krampe en pyn tydens u menstruasie, pyn tydens seks, borstepyn/gevoeligheid, pyn/ongemak in u bekken, spasma van u baarmoeder (uterus), afskeiding vanuit u vagina, droogheid/ongemak in die vagina en genitale omgewing, menstruele bloeding wat langer as 7 dae duur, bloeding na seks (hou nie verband met menstruasie nie), vreemde reuk vanuit u vagina, enige vaginale/baarmoeder bloeding, onverwant aan u gewone menstruasie, insluitend vlekking, ongereelde menstruele siklusse, erge menstruele bloeding
- gewigstoename, abnormale eierstokke, soos bepaal deur ultraklank
- bloeding nadat die toestel ingeplaas is, toestel word uitgewerp, pyn tydens die inplasingsprosedure van die toestel, toestel beweeg van waar dit geplaas is.

Ongewone en skaars newe-effekte sluit die volgende in:
- verergering van 'n geestesversteuring wat bipolêre versteuring genoem word (gevalle van buierigheid, wat strek vanaf depressiewe laagtepunte tot maniese hoogtes), selfmoordneigings
- oormatige haargroei van donker growwe hare in 'n manlike patroon, dit wil sê rondom die mond, ken, gesig, bors en rug.
- vetterige hare
- infeksie van die bindweefsel langs die baarmoeder, infeksie van die fallopius-buise, of ander gedeeltes van die vroulike voortplantingsorgane, menstruele siklus is korter as 21 dae
- swelling van die buik en swelling van die hande en voete.

Indien u enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem is nie, raadpleeg asseblief u dokter of apteker.

Pyn bloeding, of duiseligheid tydens en na inplasing. Indien hierdie simptome nie verdwyn binne 30 minute vanaf inplasing nie, is dit moontlik dat AVIBELA nie korrek ingeplaas is nie, of hierdie mag simptome van perforasie of uitwerping wees. U gesondheidsorgverskaffer moet u ondersoek om te bepaal of AVIBELA verwyder of vervang moet word.

Menstruele siklusse wat oorgeslaan word. Ongeveer 2 uit elke 10 vroue se menstruasie verdwyn na 1 jaar van AVIBELA gebruik. Indien u nie gemenstrueer het vir 6 weke tydens AVIBELA gebruik nie, skakel u gesondheidsorgverskaffer. Indien u enige bekommernis het dat u mag swanger wees, terwyl u AVIBELA gebruik, voer 'n urien-swangerskaptoets uit en skakel u gesondheidsorgverskaffer. U menstruele siklusse sal gewoonlik terugkeer na die vorige patroon, wanneer AVIBELA verwyder word.

Aanmelding van newe-effekte
Indien u newe-effekte ervaar, praat met u dokter of apteker. Dit sluit enige moontlike newe-effekte in, wat nie in hierdie inligtingsblad gelys is nie. U kan ook newe-effekte aanmeld by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word.
Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van AVIBELA in te win. U kan ook 'n epos direk na die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za om veiligheid van die produk te verseker.

5. Hoe om AVIBELA te bewaar
Bewaar alle medisyne buite die bereik van kinders.
Bewaar teen of benede 30 °C.
Bewaar in die oorspronklike verpakking. Hou die geseëlde bakkie in die buitenste kartonhouer om te beskerm teen lig. Moet nie die AVIBELA verpakking oopmaak nie. Slegs u gesondheidsorgverskaffer moet dit doen.
Moet nie gebruik na die vervaldatum wat op die etiket en die buitenste verpakking aangedui word nie. Die vervaldatum verwys na die laaste dag van daardie maand.

6. Verpakkingsinhoud en ander inligting
Wat AVIBELA bevat:
AVIBELA bevat 52 mg levonorgestrel (die aktiewe bestanddeel).
Die hormoon word bevat in 'n substans wat polidimetielsiloksaan genoem word. Dit word omring deur 'n membraan (film), wat ook vervaardig is van polidimetielsiloksaan.

Die ander bestanddele is:
Reservoir van die IUT
Silikoonbasis, stannusoktoaat, tetra-n-propielsilikaat

T-raam
Laedigtheid poli-etileen (LDPE), bariumsulfaat, polidimetielsiloksaan (PDMS) membraan, polipropileen draad, gekleur met ftalosianienato (2-) koper.

Hoe AVIBELA lyk en die verpakkingsinhoud
AVIBELA bestaan uit 'n klein T-vormige raam, wat vervaardig is van 'n plastiek, wat poli-etileen genoem word. Hierdie struktuur voorsien 'n toestel wat die hormoon geleidelik in die uterus (baarmoeder), vrystel. Daar is twee dun blou draadjies, wat vervaardig is van poli-propileen en koperftalosianien blou, wat aan die onderkant van die T-raam vasgeheg is. Dit maak maklike verwydering moontlik en laat ook u gesondheidsorgverskaffer toe om seker te maak AVIBELA is in die regte posisie geplaas.

AVIBELA met die toedieningstoestel, word vooraf gelaai, voorsien en verpak in 'n deursigtige plastiekhouer met 'n deksel. AVIBELA is beskikbaar in 'n kartonhouer as een steriele eenheid.

Eienaar van die Registrasiesertifikaat

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