PATIENT INFORMATION LEAFLET

TIBILIVE 2,5 MG

SCHEDULING STATUS

S4

TIBILIVE 2,5 mg tablets

Tibolone

TIBILIVE 2,5 mg contains sugar (lactose monohydrate 43,15 mg and mannitol 43,15 mg)

Read all of this leaflet carefully before you start taking TIBILIVE 2,5 mg

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TIBILIVE 2,5 mg has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What TIBILIVE 2,5 mg is and what it is used for
2. What you need to know before you use TIBILIVE 2,5 mg
3. How to use TIBILIVE 2,5 mg
4. Possible side effects
5. How to store TIBILIVE 2,5 mg
6. Contents of the pack and other information

1. What TIBILIVE 2,5 mg is and what it is used for

TIBILIVE 2,5 mg is a Hormone Replacement Therapy (HRT). It contains tibolone, a substance that has favourable effects on different tissues in the body, such as brain, vagina and bone. This medicine is used in postmenopausal women with at least 12 months (1 year) since their last natural period and also in women who had their ovaries removed.

Unlike some other medicines used for hormone replacement therapy, TIBILIVE 2,5 mg does not stimulate the lining of the womb. Treatment with TIBILIVE 2,5 mg therefore does not lead to monthly vaginal bleeding.

This medicine is used for:

- relief of symptoms occurring after menopause:

  During the menopause, the amount of the oestrogen produced by a woman's body drops. This can cause symptoms such as hot face, neck and chest ("hot flushes"). TIBILIVE 2,5 mg alleviates these symptoms after menopause. You will only be prescribed this medicine if your symptoms seriously hinder your daily life.
- prevention of osteoporosis:

  After the menopause some women may develop fragile bones (osteoporosis).
- improvement of bone-mineral density in post-menopausal osteoporosis:

  If you are at an increased risk of fractures due to osteoporosis and other medicines are not suitable for you, you can use TIBILIVE 2,5 mg to prevent fractures after menopause.

2. What you need to know before you take TIBILIVE 2,5 mg

Do not take TIBILIVE 2,5 mg:

- if you are hypersensitive (allergic) to tibolone, or to any of the ingredients of TIBILIVE 2,5 mg
- if you, or anyone in your family have or have ever had breast cancer, or if you are suspected of having it
- if you have or have ever had a blood clot in a vein (thrombosis), such as in the legs (deep venous thrombosis - DVT) or the lungs (pulmonary embolism)
- if you have a blood clotting disorder (such as protein C, protein S, or antithrombin deficiency), including an inherited disorder that makes your blood more likely to clot
- if you have or have ever had a liver disease and your liver function tests have not returned to normal

- if you have inherited genetic mutations: BRCA1 and BRCA2 genes, as you have a higher risk of developing cancer
- in the case of early menstrual periods (before the age of 12 years)
- if you have ever had other non-cancerous breast diseases such as atypical hyperplasia (a precancerous condition that affects cells in the breast) or lobular carcinoma in situ (abnormal cells growing in the lining of the milk glands)
- if you have ever had treatment using radiation therapy to the chest or breast
- if you have ever been exposed to diethylstilbestrol (DES), a synthetic oestrogen medicine
- if you have cancer which is sensitive to oestrogens, such as cancer of the womb lining (endometrium), or if you are suspected of having it
- if you have any unexplained vaginal bleeding
- if you have excessive thickening of the womb lining (endometrial hyperplasia) that is not being treated
- if you have or recently have had a disease caused by blood clots in the arteries, such as a heart attack, stroke or angina
- if you have a rare blood problem called “porphyria” which is passed down in families (inherited)
- if you are pregnant, think you might be pregnant or are breastfeeding your baby.

Warnings and precautions

Take special care with TIBILIVE 2,5 mg:

TIBILIVE 2,5 mg is not a contraceptive. If it is less than 12 months since your last menstrual period or you are under 50 years old, you may still need to use additional contraception to prevent pregnancy.

If you have started menopause you should not take TIBILIVE 2,5 mg until 12 months after your last natural period. If you take it sooner than this you may have irregular bleeding.

Stop taking TIBILIVE 2,5 mg and see a doctor immediately if any of the following occur:

- yellowing of your skin or the whites of your eyes (jaundice). These may be signs of a liver disease
- a large rise in your blood pressure (symptoms may be headache, tiredness, dizziness)
- migraine-like headaches which happen for the first time
- if you become pregnant
- if you notice signs of a blood clot, such as:
    - painful swelling and redness of the legs
    - sudden chest pain
    - difficulty in breathing.

Medical check-up

Your doctor will ask about your own and your family's medical history. Your doctor may decide to perform a physical examination. This may include an examination of your breasts and /or an internal examination, if necessary.

Once you have started TIBILIVE 2,5 mg therapy, you should see your doctor for regular check-ups (at least once a year). At these check-ups, discuss with your doctor the benefits and risks of continuing with TIBILIVE 2,5 mg.

Go for regular breast screening and cervical smear tests, as recommended by your doctor.

Regularly check your breasts for any changes such as dimpling of the skin, changes in the nipple, or any lumps you can see or feel.

If you have ever had any of the following problems, tell your doctor before you start the treatment, as these may return or become worse during treatment with TIBILIVE 2,5 mg. If so, you should see your doctor more often for check-ups:

- fibroids inside your womb, growth of the womb lining outside your womb (endometriosis) or a history of excessive growth of the womb lining (endometrial hyperplasia)
- increased risk of developing blood clots (see Blood clots in a vein (thrombosis) below)

- increased risk of getting an oestrogen-sensitive cancer (such as having a mother, sister or grandmother who has had breast cancer)
- high blood pressure
- a liver disorder, such as a benign liver tumour
- diabetes
- gallstones or a very high level of fat in your blood (triglycerides)
- migraine or severe headaches
- a disease of the immune system that affects many organs of the body (systemic lupus erythematosus, SLE)
- epilepsy
- asthma
- a disease affecting the eardrum and hearing (otosclerosis).

Hormone Replacement Therapy (HRT) and cancer:

Excessive thickening of the lining of the womb (endometrial hyperplasia) and cancer of the lining of the womb (endometrial cancer):

There have been reports of an increased cell growth or cancer of the lining of the womb in women using TIBILIVE 2,5 mg. The risk of cancer of the lining of the womb increases the longer you take the medicine.

Irregular bleeding

You may have irregular bleeding or drops of blood (spotting) during the first months of taking TIBILIVE 2,5 mg. Talk to your doctor if the bleeding or spotting:

- carries on for more than the first 3 months
- starts after you have been taking TIBILIVE 2,5 mg for more than 3 months
- carries on even after you've stopped taking TIBILIVE 2,5 mg.

Breast cancer

TIBILIVE 2,5 mg contains tibolone which has combined estrogenic and progestogenic effects and therefore, on prolonged use, may increase the risk of developing breast cancer.

The risk is steadily increased with duration of use, and women taking TIBILIVE 2,5 mg have a lower risk than women using combined menopausal hormone therapy (MHT) and a comparable risk with oestrogen-only MHT.

All women on TIBILIVE 2,5 mg should receive yearly breast examinations by a healthcare provider and perform monthly breast self-examinations. See your doctor if you notice any changes such as:

- dimpling or sinking of the skin
- changes in the nipple
- any lumps you can see or feel

Ovarian cancer

Ovarian cancer is rare – much rarer than breast cancer. A slightly increased risk of ovarian cancer has been reported in women taking hormone replacement therapy for at least 5 to 10 years.

With use of TIBILIVE 2,5 mg, the increased risk of ovarian cancer is similar to other types of HRT.

Effect of HRT on heart and circulation

Blood clots in a vein (thrombosis)

The risk of blood clots in the veins is about 1,3 to 3-times higher in HRT users than in non-users, especially during the first year of taking it.

Blood clots can be serious, and if one travels to the lungs, it can cause chest pain, breathlessness, fainting or even death.

You are more likely to get a blood clot in your veins as you get older and if any of the following applies to you. Inform your doctor if any of these situations apply to you:

- you are pregnant or recently had a baby
- you use oestrogens

- you are unable to walk for a long time because of major surgery, injury or illness (see also section 3, if you need to have surgery)
- you are seriously overweight (BMI > 30 kg/m^2)
- you have systemic lupus erythematosus (SLE)
- you have cancer
- you have any blood clotting problem that needs long-term treatment with a medicine used to prevent blood clots
- if any of your close relatives has ever had a blood clot in the leg, lung or another organ.

For signs of a blood clot, see the section above: Stop taking TIBILIVE 2,5 mg and see a doctor immediately.

You may need to stop taking TIBILIVE 2,5 mg about 4 to 6 weeks before you have an operation to reduce the risk of a blood clot.

Heart disease (heart attack)

There is no evidence that HRT or TIBILIVE 2,5 mg will prevent a heart attack.

Stroke

Recent research suggests that HRT and TIBILIVE 2,5 mg slightly increases the risk of having a stroke. The increased risk is seen mainly in post-menopausal women over 60 years old.

Other conditions

Oestrogens may cause fluid retention, and therefore patients with heart or kidney disease should be carefully observed.

If you have high levels of fats called triglycerides in your blood (hypertriglyceridaemia), your doctor will closely monitor this condition as there is a risk of developing pancreatitis during TIBILIVE 2,5 mg therapy.

If you need a blood test, tell your doctor or the laboratory staff that you are taking TIBILIVE 2,5 mg because it can affect the results of some tests.

TIBILIVE 2,5 mg will not prevent memory loss. There is some evidence of a higher risk of memory loss in women who start using HRT after the age of 65. Speak to your doctor for advice.

Other medicines and TIBILIVE 2,5 mg

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Some medicines may interfere with the effect of TIBILIVE 2,5 mg. This might lead to irregular bleeding. This applies to the following medicines:

- Medicines against blood clotting (such as warfarin)
- Medicines for epilepsy (such as phenobarbitone, phenytoin and carbamazepine)
- Medicines for tuberculosis (such as rifampicin)
- Herbal remedies containing St John's Wort (*Hypericum perforatum*).

If you are going to have an operation, make sure your doctor knows about it. You may need to stop taking HRT about 4 to 6 weeks before the operation, to reduce the risk of a blood clot. Your doctor will tell you when you can start taking HRT again.

TIBILIVE 2,5 mg with food and drink

TIBILIVE 2,5 mg can be taken with or without food.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking TIBILIVE 2,5 mg.

TIBILIVE 2,5 mg should not be used during pregnancy. Stop taking TIBILIVE 2,5 mg if you suspect or find out you are pregnant.

TIBILIVE 2,5 mg is contraindicated in breastfeeding.

Driving and using machines

TIBILIVE 2,5 mg has no known effect on the ability to drive or use machines.
It is not always possible to predict to what extent TIBILIVE 2,5 mg may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TIBILIVE 2,5 mg affects them.

TIBILIVE 2,5 mg contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking TIBILIVE 2,5 mg.

3. How to take TIBILIVE 2,5 mg

Do not share medicines prescribed for you with any other person. Always use TIBILIVE 2,5 mg exactly as your doctor has instructed. You should check with your doctor or pharmacist if you are unsure.

Adults:

The usual dose is one tablet daily, preferably at the same time each day. Swallow the tablet whole with a little water.

Natural menopause:

Wait for 12 months after your last period before you start taking TIBILIVE 2,5 mg.

Menopause as a result of surgery:

If you have had a hysterectomy or you are being treated for endometriosis you can start taking TIBILIVE 2,5 mg immediately.

Your doctor will tell you how long your treatment with TIBILIVE 2,5 mg will last. Do not stop treatment early because your symptoms may return.

If you have the impression that the effect of TIBILIVE 2,5 mg is too strong or too weak, tell your doctor or pharmacist.

If you take more TIBILIVE 2,5 mg than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:

- nausea, vomiting and vaginal bleeding

Take this leaflet and the rest of the remaining TIBILIVE 2,5 mg with you so the doctor will know what you have taken.

If you forget to take TIBILIVE 2,5 mg

If you forget to take TIBILIVE 2,5 mg, take as soon as you remember on the same day, unless you are more than 12 hours late. If you are more than 12 hours late, just skip it, and take your next tablet the next day. Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

TIBILIVE 2,5 mg can have side effects.

Not all side effects reported for TIBILIVE 2,5 mg are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using

TIBILIVE 2,5 mg, please consult your healthcare provider for advice.

If any of the following happens, stop using TIBILIVE 2,5 mg and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TIBILIVE 2,5 mg. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- your blood pressure rises
- your skin or the whites of your eyes go yellow (jaundice)
- you suddenly have migraine-type headaches (see section 2 above)
- you have signs of a blood clot (painful swelling and redness of the legs, sudden chest pain, difficulty in breathing)
- stroke (presenting with symptoms such as trouble walking, speaking and understanding as well as paralysis or numbness of the face, arm or leg).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- lower abdominal pain
- abnormal hair growth
- vaginal problems such as discharge, itching, irritation, vaginal bleeding or spotting, breast tenderness, pelvic pain, thickening of the lining of the womb or the lining of the cervix
- weight increase, abnormal pap-smear test results

Less frequent side effects:

- fluid retention (swollen hands, ankles or feet)
- acne, itchy skin
- gastrointestinal upset, abdominal discomfort
- breast discomfort, fungal infection, vaginal thrush (yeast infection), nipple pain
- memory loss

The following side effects have been reported but the frequency for them to occur is not known:

- depression
- dizziness, headache, migraine
- visual disturbances, blurred vision
- liver problems
- skin problems such as rash or itching, scaly patches and red skin
- joint pain, muscle pain

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report any side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/Publications/Index/8 or https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/.

By reporting side effects, you can help provide more information on the safety of TIBILIVE 2,5 mg. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

5. How to store TIBILIVE 2,5 mg

Store all medicines out of reach of children.

Store at or below 30 °C

Store in the original package in order to protect from light and moisture.

Do not use after the expiry date stated on the carton. Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TIBILIVE 2,5 mg contains:

Each tablet contains 2,5 mg of tibolone.

The other ingredients are:

Tablet cores:

Ascorbyl palmitate, lactose monohydrate, magnesium stearate, mannitol, potato starch.

What TIBILIVE 2,5 mg looks like and contents of the pack

White to off-white round uncoated tablets without any marking.

TIBILIVE 2,5 mg tablets are packed in PVC/Aluminium foil blisters placed in outer carton. Each carton contains 28 or 30 tablets.

Holder of Certificate of Registration

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This leaflet was last revised in

07 November 2022

Registration number

A52/21.13/0078