PATIENT INFORMATION LEAFLET

RUBY

SCHEDULING STATUS:

S3

RUBY film coated tablets

Drospirenone and Ethinylestradiol

(lactose monohydrate 62,00 mg and lactose anhydrous 89,50 mg).

Read all of this leaflet carefully before you start taking RUBY

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- RUBY 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 RUBY is and what it is used for

RUBY contains two different female hormones - drospirenone and ethinylestradiol.

RUBY, a combined oral contraceptive containing specific hormones is used to prevent pregnancy.

2. What you need to know before you take RUBY

Do not take RUBY:

- if you are hypersensitive (allergic) to drospirenone, ethinylestradiol or any of the other ingredients of RUBY (see section 5)
- if you have thrombosis (formation of blood clots in the vessels leading to deep venous thrombosis, pulmonary embolism, heart attack or stroke), are at risk of thrombosis or have previously had thrombosis
- if you have any of the following diseases which may increase your risk of a clot in the arteries:
    - severe diabetes with blood vessel damage
    - very high blood pressure
    - a very high level of fat in the blood (high cholesterol)
    - if you are a heavy smoker
- if you have jaundice (yellowing of the skin), a severe liver disorder or a liver tumour
- if you have a kidney disorder
- if you have any malignant tumours of the breast or womb
- if you have vaginal bleeding of unknown origin
- if you suffer from migraine headaches
- if you are pregnant or suspecting pregnancy or breastfeeding your baby (see Pregnancy and breastfeeding)
- if you need an operation or are off your feet for a long time.

If any of these conditions appear for the first time whilst using RUBY, stop taking it at once and consult your doctor or pharmacist.

Warnings and precautions

Take special care with RUBY:

- if you are at risk of a heart or blood vessel disease (cardiovascular disease) and thrombosis (risk factors include increased age, thrombosis in the family, no movement for a long time**,** overweight, smoking, moderate disturbance of the fat metabolism, high blood pressure, heartbeat disturbances)
- if you have a family history of cervical or breast cancer
- if you are taking medicines that affect the potassium levels in your body (e.g. certain blood pressure and pain medicine)
- if you have the following conditions: jaundice, gallstones, porphyria, systemic lupus erythematosus, haemolytic uremic syndrome, Sydenham's chorea, herpes gestationis or otosclerosis related hearing loss. These conditions may develop or worsen with the use of RUBY
- if you have a hereditary condition of angioedema (swelling of the area beneath the skin)
- if you start to vomit or have severe diarrhoea after 3 to 4 hours of taking RUBY
- if you suffer from a liver disorder.
- if you are a diabetic patient
- if you suffer from a disease called Crohn's disease or ulcerative colitis
- if you have patchy brown or dark brown skin discolouration that usually occurs on the face resulting from hormonal changes (chloasma)
- if you suffer from asthma.

RUBY, like other hormonal contraceptives, will not protect you against HIV infection (AIDS) and other sexually transmitted diseases.

Effective contraception may be reduced in missed doses, vomiting or severe diarrhoea (see section 3 How to take RUBY), or when taking other medicines (see Other medicines and RUBY).

Children and adolescents:

RUBY is not intended for use in females whose periods have not yet started.

Other medicines and RUBY

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

The following medicines have the potential to increase potassium levels:
ACE inhibitors, angiotensin II receptor antagonists (used in the treatment of high blood pressure), aldosterone antagonists (for example spironolactone used in the treatment of chronic heart failure and hyperaldosteronism) and anti-inflammatory agents (used in the
treatment of pain and inflammation). You should test your potassium levels on a regular basis
if you are using any of the above-mentioned medicine for a long time.
Some medicines can make RUBY less effective in preventing pregnancy. These include medicines used in the treatment of epilepsy (phenytoin, primidone, felbamate, carbamazepine, oxcarbazepine) barbiturates, epilepsy and migraines (topiramate), high blood pressure (bosentan), tuberculosis (TB) (rifampicin), HIV infections (ritonavir, nevirapine and efavirenz), fungal infections (griseofulvin), antibiotics (ampicillin and tetracyclines) and the herbal remedy St. John's Wort (used for depression) may decrease the effect of RUBY.

If you are on long-term antibiotic therapy or using any of the above medicines whilst taking RUBY you will have to use an additional method of birth-control (contraception) and for a
period of 28 days (especially with rifampicin) after you have stopped the medication, in order to avoid unplanned pregnancy.
Alternative birth control methods are advisable if you are on long-term antibiotic therapy.

During the use of RUBY, it may be necessary to alter the dose of medicine required to treat diabetes.
RUBY may increase the effects of ciclosporin (used to prevent organ rejection) or decrease the effects

of lamotrigine (used to treat epilepsy).

In case of blood sampling, you should tell your healthcare that you are taking an oral contraceptive, because RUBY may affect the results of the laboratory tests.

In case of missing your period, you can do a pregnancy test, the result of this is not affected by the pill.

If you have taken the pill as prescribed, you have not had any stomach upset accompanied with vomiting and you have not taken other medicines, pregnancy is very unlikely. However, before continuation of the treatment, pregnancy should be excluded.

RUBY with food and drink

RUBY may be taken with or without food.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding your baby, please consult your healthcare provider for advice before using RUBY.

RUBY should not be used during pregnancy.

The active ingredients in RUBY may appear in breast milk. RUBY may reduce the amount and change the composition of breast milk and is therefore not recommended during breastfeeding.

Driving and using machines:

RUBY is not expected to interfere with your ability to drive or use machines.

It is not always possible to predict to what extent RUBY 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 RUBY affects them.

RUBY contains lactose

RUBY contains lactose. Patients with rare hereditary problems of galactose intolerance or glucose-galactose malabsorption should not take RUBY.

RUBY contains lactose which may influence the control of your blood sugar if you have diabetes mellitus.

3. How to take RUBY

Do not share medicines prescribed for you with any other person.

Always use RUBY exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

Taking RUBY for the first time:

The first tablet should be started on the first day of the menstrual cycle (day 1 of the cycle) by selecting the appropriate tablet for that day of the week (e.g. MON for Monday).

One tablet should be taken daily (preferably after the evening meal or at bedtime) for 28 consecutive days. The tablet is swallowed whole with some liquid.

Withdrawal bleeding usually starts on day 2 to 3 after starting on the inactive white tablets and may not have finished before the next pack is started.

Each subsequent pack is started the day after the last tablet of the current pack. If RUBY is started during the last part of the week, the very first cycle may be slightly shortened.

How to start RUBY

No preceding hormonal contraceptive uses (in the past month)

Tablet-taking has to start on day 1 of natural cycle (i.e. the first day of the menstrual bleeding).

An additional barrier method is recommended for the first 7 days of tablet-taking during the first cycle.

Changing from another combined oral contraceptive to RUBY

The first RUBY tablet should be taken on the day after the last active tablet of the previous combined oral contraceptive, but at the latest on the day following the usual tablet-free or inactive tablet interval of the previous combined oral contraceptive.

Changing from a Progestogen-only-Pill (POP or mini-pill, injection, implant)

From mini-pills it can be changed to RUBY on any day of the menstrual cycle, from an implant on the day after its removal and from an injectable when the next injection would be due.

In all these cases additional contraceptive precautions are required for the first 7 days of tablet-taking.

Following 1st trimester abortion or miscarriage

Oral contraception may be started immediately. Additional contraceptive precautions are not required.

Following delivery or 2nd trimester abortion or miscarriage

For use in lactation – see section 2 Pregnancy and breastfeeding.

Oral contraception can be started by non-lactating women 21 to 28 days after a delivery or 2nd trimester abortion. If oral contraception is started later, one of the barrier methods as additional contraceptive precaution is also required for the first 7 days.

If intercourse has already taken place, pregnancy should be excluded before tablet intake is started, or it should be delayed until the first menstrual bleeding.

Management of missed tablets:

Tablet-taking must never be discontinued for longer than 7 days. Uninterrupted tablet-taking for 7 days are required to attain adequate suppression of the hypothalamic-pituitary-ovarian axis.

Missing 1 yellow active tablet within 12 hours

Contraceptive protection is not reduced, and additional contraceptive precautions are not required. Take the tablet as soon as you remember and take the next tablet on the scheduled time, even if it means taking 2 tablets in one day.

Missing 1 yellow active tablet which exceeds 12 hours

Contraceptive protection can be reduced. Additional contraceptive precautions are required, and you must follow the 7-day rule. Read the sections on '*Extra contraceptive precautions' and 'The 7-day rule' carefully.* Take the tablet as soon as you remember and take the next tablet on the scheduled time, even if it means taking 2 tablets in one day.

Missing 2 yellow active tablets in a row during the first or second week

Take 2 tablets on the day you remember and 2 tablets the following day, continuing the regular dosing schedule.

Additional contraceptive precautions are required and you must follow the 7-day rule. Read the sections on '*Extra contraceptive precautions' and 'The 7-day rule" carefully.*

Missing more than 2 yellow active tablets in a row during the third week

Using day 1 start: Start a new cycle on the day you remember, discarding remaining doses for current cycle. Additional contraceptive precautions are required, and you must follow the 7-day rule. Read the sections on '*Extra contraceptive precautions' and 'The 7-day rule' carefully.* Consult your healthcare professional if 2 menstrual periods are missed.

Extra contraception precautions:

If extra contraceptive precautions are required either:

- ***don't have sex, or***
- ***use a cap plus spermicide, or a condom.***

Do not use temperature or rhythm methods as extra contraceptive precautions. This is because oral contraceptives disrupt the usual menstrual cycle changes such as changes in temperature and cervical mucus.

The 7-day rule:

If you are more than 12 hours late taking a tablet, or if you have vomited, or if your doctor advises you to follow the 7-day rule because you are taking certain medicines.

Take extra contraceptive precautions during the next 7 days, but if these days run beyond the end on the yellow active tablets, the 7 white inactive tablets must not be taken (i.e. discard the current pack after taking the last yellow active tablet). Start a new pack on the next day with the first yellow active tablet. You can continue to take your tablets as usual. Read the section '*Extra contraception precautions*' carefully.

Do not leave a gap between the packs. Your menstrual period will occur after you have completed the second pack. If your period does not occur, consult your doctor before resuming the next pack.

Missing any of the white inactive tablets can be ignored but beginning a new cycle on time is essential.

What to do if you start vomiting or have severe diarrhoea:

If you start vomiting within 3 to 4 hours of taking RUBY, the medicine may be less effective as this is like missing a tablet.

Speak to your doctor or pharmacist on how to continue taking RUBY.

You want to delay a period

You can delay your period if you start with your next pack of RUBY tablets immediately after finishing the active yellow tablets of your current pack (do not take the inactive white tablets). You can continue

with this pack for as long as you wish, e.g., until this pack is empty, to get a period approximately 3 weeks later than usual. While using the second pack, you may have some breakthrough bleeding or spotting on active tablet-taking days.

You have unexpected bleeding:

With all pills, for the first few months, you can have irregular vaginal bleeding (spotting or breakthrough bleeding) outside the 7-day pill-free days. If this bleeding lasts longer than a few months, or if it begins after some months, your doctor must investigate the cause.

Your doctor will tell you how long your treatment with RUBY will last. Do not stop treatment early because the risk of unwanted pregnancy is increased.

If you have the impression that the effect of RUBY is too strong or too weak, tell your doctor or pharmacist.

If you take more RUBY 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 slight vaginal bleeding in young girls.

If you forget to take RUBY:

If you forget to take RUBY, take a dose as soon as you remember, then continue to take RUBY at the usual times.

If you stop taking RUBY

The risk of unplanned pregnancy is increased. If you do not want to become pregnant, alternate

contraception should be taken.

4. Possible side effects

RUBY can have side effects. Not all side effects reported for RUBY are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using RUBY, please consult healthcare provider for advice.

If any of the following happens, stop using RUBY 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RUBY. 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:

- tight chest or wheezing
- breast pain or tenderness, any lumps you can see or feel
- signs of a thrombosis such as severe pain in the chest which may reach the left arm, unusually severe pain in the legs, weakness or numbness in any part of your body, breathlessness, unusual cough, especially if you cough up blood, dizziness or fainting, visual disturbances, disturbed hearing or speech, sensory defect, migraine for the first time or your migraine gets worse, unusual, recurrent or constant headache
- if you experience a heart attack or stroke
- jaundice (yellowing of the skin)

- sudden severe stomach pains
- unusual heavy vaginal bleeding or if you miss your period twice in arrow
- if you suspect you are pregnant
- high or low blood pressure.

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:

- mood disturbances, depression, uncontrollable laughing or crying at inappropriate times, decrease and loss of interest in sexual intercourse
- depressed mood and depression are well-known undesirable effects of hormonal contraceptive use. Depression can be serious and is a well-known risk factor for suicidal behaviour and suicide. You should contact your doctor or pharmacist in case of mood changes and depressive symptoms, including shortly after you have started the treatment.
- decrease and loss of interest in sexual intercourse
- headache, migraine
- nausea, drowsiness
- menstrual disorders, bleeding between menstrual cycles, breakthrough bleeding or spotting, breast tenderness, breast pain.

Less frequent side effects:

- increase of interest in sexual intercourse
- vomiting, diarrhoea
- acne, eczema, painful red skin rash or sores, hair loss, abnormal hair growth on the face and body

- vaginal (yeast) infection
- unusual breast enlargement
- fluid retention, weight gain or weight loss, fatigue, fever.

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

- inflammation of the pancreas, gallstones, how well your body's cells absorb glucose (changes in glucose tolerance), inflammatory bowel disease (Crohn's disease, ulcerative colitis)
- liver tumours or changes in liver function tests
- hearing impairment
- harmful blood clots in a vein or artery for example, in a leg or foot (i.e. DVT), heart attack stroke, mini-stroke or temporary stroke-like symptoms, known as a transient ischaemic attack (TIA).

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 or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the online service for adverse drug reaction by following the link https://www.sahpra.org.za/Publications/Index/8. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product. By reporting side effects, you can help provide more information on the safety of RUBY

5. How to store RUBY

Store at or below 25 ºC.

Store all medicines out of reach of children.

Keep in outer container until required for use.

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 RUBY contains

The active substances are drospirenone and ethinylestradiol.

Each active film coated tablet contains 3 mg drospirenone and 0,03 mg ethinylestradiol.

RUBY contains sugar (lactose monohydrate 62,00 mg and lactose anhydrous 89,50 mg).

The other ingredients are:

Tablet core:

Crospovidone (XL and XL-10), magnesium stearate, maize starch, polysorbate 80, povidone K-30, pregelatinised starch.

Coating:

Opadry II yellow, Opadry II white.

What RUBY looks like and contents of the pack

Film coated tablet.

21 round yellow film coated tablets and. 7 round white film coated tablets.

RUBY is packed into plain aluminium/PVC/PVDC foil blister strips containing 28 tablets packed in an outer carton.

Holder of Certificate of Registration

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