APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S3

RUBY, 3 mg/0,03 mg, 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, nurse or other healthcare provider.
- 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

6. Contents of the pack and other information

1. What RUBY is and what it is used for

RUBY contains two different female hormones - drospirenone and ethinylestradiol.

RUBY, 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 6)
- if you know you have a disorder affecting your blood clotting – for instance, protein C deficiency, protein S deficiency, antithrombin-III deficiency, Factor V Leiden or antiphospholipid antibodies
- 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 or an increased tendency to form clots (thrombophilia)
- 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), active liver disease or 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 or if you have a family history of breast cancer or non-cancerous breast disease
- if you inherited gene (BRCA1 and BRCA2) that may change and increase the likelihood to get breast, ovarian, and other cancers
- if you have vaginal bleeding of unknown origin
- if you had early menstrual periods (before the age of 12 years)
- if you previously received a cancer treatment that uses high doses of radiation to kill cancer cells and shrink tumours
- if you previously used a medicine containing Diethylstilbestrol (a synthetic form of the female hormone estrogen) which is prescribed for related to complications during pregnancy
- 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 healthcare provider.

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 elevated levels of fat in the blood (hypertriglyceridaemia) or a positive family history for this condition. Hypertriglyceridaemia has been associated with an increased risk of developing pancreatitis (inflammation of the pancreas)
- 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).

RUBY contains an estrogen, and drospirenone, which may increase the risk of developing breast cancer in women between 40 – 59 years, during long-term use. All women on hormone therapy should receive yearly breast examinations by a doctor and perform monthly self-examinations of their breasts (see Do not take RUBY).

Blood clots:

RUBY increases your risk of developing a blood clot compared with not using one. In rare cases a blood clot can block vessels and cause serious problems.

Blood clots can develop:

- in veins (referred to as a ‘venous thrombosis’, ‘venous thromboembolism’ or VTE)
- in the arteries (referred to as an ‘arterial thrombosis’, ‘arterial thromboembolism’ or ATE)

Recovery from blood clots is not always complete. Rarely, there may be serious lasting effects or, very rarely, they may be fatal.

It is important to remember that the overall risk of a harmful blood clot due to RUBY is small.

How to recognise a blood clot:

Seek urgent medical attention if you notice any of the following signs or symptoms:

Are you experiencing any of these signs?	**What are you possibly suffering from?**
swelling of one leg or along a vein in the leg or foot especially when accompanied by: • pain or tenderness in the leg which may be felt only when standing or walking • increased warmth in the affected leg • change in colour of the skin on the leg e.g. turning pale, red or blue	Deep vein thrombosis

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• sudden unexplained breathlessness or rapid breathing • sudden cough without an obvious cause, which may bring up blood; • sharp chest pain which may increase with deep breathing; • severe light headedness or dizziness; • rapid or irregular heartbeat • severe pain in your stomach; If you are unsure, talk to a doctor as some of these symptoms such as coughing or being short of breath may be mistaken for a milder condition such as a respiratory tract infection (e.g. a 'common cold').	Pulmonary embolism
Symptoms most commonly occur in one eye: • immediate loss of vision or • painless blurring of vision which can progress to loss of vision	Retinal vein thrombosis (blood clot in the eye)
• chest pain, discomfort, pressure, heaviness • sensation of squeezing or fullness in the chest, arm or below the breastbone; • fullness, indigestion or choking feeling; • upper body discomfort radiating to the back, jaw, throat, arm and stomach; • sweating, nausea, vomiting or dizziness; • extreme weakness, anxiety, or shortness of breath; • rapid or irregular heartbeats	Heart attack

• sudden weakness or numbness of the face, arm or leg, especially on one side of the body; • sudden confusion, trouble speaking or understanding; • sudden trouble seeing in one or both eyes; • sudden trouble walking, dizziness, loss of balance or coordination; • sudden, severe or prolonged headache with no known cause; • loss of consciousness or fainting with or without seizure. Sometimes the symptoms of stroke can be brief with an almost immediate and full recovery, but you should still seek urgent medical attention as you may be at risk of another stroke.	Stroke
• swelling and slight blue discolouration of an extremity; • severe pain in your stomach (acute abdomen)	Blood clots blocking other blood vessels

Blood clots in a vein:

What can happen if a blood clot forms in a vein?

- RUBY has been connected with an increase in the risk of blood clots in the vein (venous thrombosis). However, these side effects are rare. Most frequently, they occur in the first year of use of a RUBY.

- If a blood clot forms in a vein in the leg or foot it can cause a deep vein thrombosis (DVT).
- If a blood clot travels from the leg and lodges in the lung it can cause a pulmonary embolism (PE).
- Very rarely a clot may form in a vein in another organ such as the eye (retinal vein thrombosis).

When is the risk of developing a blood clot in a vein highest?

The risk of developing a blood clot in a vein is highest during the first year of taking a RUBY for the first time. The risk may also be higher if you restart taking a RUBY (the same product or a different product) after a break of 4 weeks or more.

After the first year, the risk gets smaller but is always slightly higher than if you were not using a RUBY.

- When you stop RUBY your risk of a blood clot returns to normal within a few weeks.

What is the risk of developing a blood clot?

The risk depends on your natural risk of VTE and the type of combined hormonal contraceptive you are taking.

The overall risk of a blood clot in the leg or lung (DVT or PE) with RUBY is small.

The risk of having a blood clot will vary according to your personal medical history

Factors that increase your risk of a blood clot in a vein

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The risk of a blood clot with RUBY is small but some conditions will increase the risk. Your risk is higher:

- if you are very overweight (body mass index or BMI over 30kg/m^2);
- if one of your immediate family has had a blood clot in the leg, lung or other organ at a young age (e.g. below the age of about 50). In this case you could have a hereditary blood clotting disorder;
- if you need to have an operation, or if you are off your feet for a long time because of an injury or illness, or you have your leg in a cast. The use of RUBY may need to be stopped several weeks before surgery or while you are less mobile. If you need to stop RUBY ask your doctor when you can start using it again.
- as you get older (particularly above about 35 years);
- if you gave birth less than a few weeks ago.

The risk of developing a blood clot increases the more conditions you have.
Air travel (>4 hours) may temporarily increase your risk of a blood clot, particularly if you have some of the other factors listed.
It is important to tell your doctor if any of these conditions apply to you, even if you are unsure. Your doctor may decide that RUBY needs to be stopped.

If any of the above conditions change while you are using RUBY, for example a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your doctor.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusually severe abdominal pain.

Blood clots in an artery

What can happen if a blood clot forms in an artery?

Like a blood clot in a vein, a clot in an artery can cause serious problems. For example, it can cause a heart attack or a stroke.

Factors that increase your risk of a blood clot in an artery

It is important to note that the risk of a heart attack or stroke from using RUBY is very small but can increase:

- with increasing age (beyond about 35 years);
- if you smoke. When using RUBY, you are advised to stop smoking. If you are unable to stop smoking and are older than 35 your doctor may advise you to use a different type of contraceptive;
- if you are overweight;
- if you have high blood pressure;
- if a member of your immediate family has had a heart attack or stroke at a young age (less than about 50). In this case you could also have a higher risk of having a heart attack or stroke;
- if you, or someone in your immediate family, have a high level of fat in the blood (cholesterol or triglycerides);

- if you get migraines, especially migraines with aura;
- if you have a problem with your heart (valve disorder, disturbance of the rhythm called atrial fibrillation);
- if you have diabetes.

If you have more than one of these conditions or if any of them are particularly severe the risk of developing a blood clot may be increased even more.

If any of the above conditions change while you are using RUBY, for example you start smoking, a close family member experiences a thrombosis for no known reason; or you gain a lot of weight, tell your
doctor.

RUBY and cancer

Breast cancer has been observed slightly more often in women using combination pills, but it is not known whether this is caused by the treatment. For example, it may be that more tumours are detected in
women on combination pills because they are examined by their doctor more often. The risk of breast tumours becomes gradually less after stopping the combination hormonal contraceptives. It is important
to regularly check your breasts and you should contact your doctor if you feel any lump. benign liver tumours, and in even fewer cases malignant liver tumours have been reported in pill users. Contact your doctor if you have unusually severe abdominal pain.

Psychiatric disorders

Some women using RUBY have reported depression or depressed mood. Depression can be serious and may sometimes lead to suicidal thoughts, if you experience mood changes and depressive symptoms contact your doctor for further medical advice as soon as possible.

Bleeding between periods

During the first few months that you are taking RUBY, you may have unexpected bleeding (bleeding outside the seven pill-free days). If this bleeding occurs for more than a few months, or if it begins after some months, contact your doctor as they must find out if anything is wrong.

What to do if no bleeding occurs during the seven pill-free days

If you have taken all the tablets correctly, have not had vomiting or severe diarrhoea and you have not taken any other medicines, it is highly unlikely that you are pregnant.

If the expected bleeding does not happen twice in succession, you may be pregnant. Contact your doctor immediately. Only start the next strip if you are sure that you are not pregnant.

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.

If you are taking etoricoxib (used in the treatment arthritis, arthrosis) at doses of 60 to 120 mg/day, or ketoconazole (used in the treatment of fungal infections), the effects of RUBY have been shown to be increased.

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).

RUBY may increase the effects of theophylline (used to treat breathing problems) and tizanidine (used to treat muscle pain and/or muscle cramps).

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, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other 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.

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RUBY contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take RUBY

Do not share medicines prescribed for you with any other person.
Always take/use RUBY exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

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, or combination contraceptive vaginal ring or patch 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.

In case a vaginal ring or transdermal patch has been used, the woman should start using RUBY preferably on the day of removal, but at the latest when the next application would have been due.

Changing from a Progestogen-only-Pill (POP or mini-pill, injection, implant or a progestogen-releasing intrauterine system IUS)

From mini-pills it can be changed to RUBY on any day, from an implant or intrauterine system on the day of 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.

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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.

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.

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If you forget to take RUBY

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.

If you are **less than 12 hours late** taking a tablet, the protection against pregnancy is not reduced.
Take the tablet as soon as you remember and then take the following tablets again at the usual time.

If you are **more than 12 hours late** taking a tablet, the protection against pregnancy may be reduced.
The greater the number of tablets you have forgotten, the greater is the risk of becoming pregnant.

The risk of incomplete protection against pregnancy is greatest if you forget a tablet at the beginning or at the end of the strip. Therefore, you should keep to the following rules:

More than one tablet forgotten in this strip: Contact your doctor.

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One tablet forgotten between days 1 - 7

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time and use extra precautions for the next 7 days, for example, a condom. If you have had sex in the week before forgetting the tablet you may be pregnant. In that case, contact your doctor.

One tablet forgotten between days 8 – 14

Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. The protection against pregnancy is not
reduced, and you do not need to take extra precautions. If you forget more than one tablet use an additional barrier method such as a condom for 7 days.

One tablet forgotten between days 15 - 21

You can choose between two possibilities:

1. Take the forgotten tablet as soon as you remember, even if that means that you have to take two tablets at the same time. Continue taking the tablets at the usual time. Instead of having seven pill-free days start the next strip as soon as you have taken the last tablet.

   Most likely, you will have a period at the end of the second strip – but you may also have light or menstruation-like bleeding during the second strip.

2. You can also stop the tablets and go directly to the tablet-free period (record the day on which you forgot your tablet). If you want to start a new strip on the day you always start, make the tablet-free period less than 7 days.

If you follow one of these two recommendations, you will remain protected against pregnancy.

If you have forgotten any of the tablets in a strip, and you do not have a bleeding during the first tablet-free period, you may be pregnant. Contact your doctor before you start the next strip.

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 your doctor, pharmacist or other healthcare professional 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 a row
- 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
- headache, migraine
- nausea, drowsiness, stomach pain
- menstrual disorders, bleeding between menstrual cycles, breakthrough bleeding or spotting, breast tenderness, breast pain, vaginal discharge.

Less frequent side effects:

- asthma
- increase of interest in sexual intercourse
- contact lens intolerance (pain, irritation, or significant discomfort from using contact lenses)

- 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)
- darker skin patches that primarily affect the face and other sun-exposed areas (chloasma)
- 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 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 or nurse. You can also report side effects to SAHPRA via the online service for adverse drug reaction reporting by following the link: https://www.sahpra.org.za/document/adverse-drug-reactions-and-quality-problem-reporting-form/

https://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of RUBY.

You can also send an email directly to the company,

pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store RUBY

Store all medicines out of reach of children.

Store at or below 25 ºC.

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).

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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 yellow active tablet:

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

Tablet core white inactive tablet:

Magnesium stearate, povidone K-30

Coating active tablet, Opadry II yellow:

Iron oxide yellow (E172), macrogol 3350, polyvinyl alcohol – partially hydrolysed, talc, titanium dioxide (E171).

Coating inactive tablet, Opadry II white:

Polyvinyl alcohol, titanium dioxide (E171).

What RUBY looks like and contents of the pack

Film coated tablet.

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

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

Holder of Certificate of Registration

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