## 1.3.2 PATIENT INFORMATION LEAFLET

**SCHEDULING STATUS**

**S3**

**ROVULUM 2 mg film coated tablets**

**Dienogest**

**Contains sugar: Lactose monohydrate 57,2 mg**

**Read all of this leaflet carefully before you start taking ROVULUM**

- 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.
- ROVULUM 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 ROVULUM is and what it is used for
2. What you need to know before you take ROVULUM
3. How to take ROVULUM
4. Possible side effects
5. How to store ROVULUM
6. Contents of the pack and other information


### 1. What ROVULUM is and what it is used for

ROVULUM belongs to a group of medicines called progestogens. ROVULUM contains a hormone, the progestogen dienogest.

ROVULUM is a medicine used for the treatment of endometriosis (painful symptoms due to displaced tissue of the lining of the womb).

## 2. What you need to know before you take ROVULUM

**Do not take ROVULUM:**

- if you are hypersensitive (allergic) to dienogest or any of the other ingredients of ROVULUM (listed in section 6),
- if you are pregnant or think you might be pregnant,
- if you are breastfeeding,
- if you are suffering from a blood clot (thromboembolic disorder) in your veins,
- if you have or have ever had a severe arterial disease, including cardiovascular disease, such as a heart attack, stroke or heart disease which causes a reduced blood supply (angina pectoris),
- if you have diabetes with blood vessel damage,
- if you have or have ever had severe liver disease (and your liver function values have not returned to normal). Symptoms of liver disease may be yellowing of the skin and/or itching of the whole body,
- if you have or have ever had a benign (non-cancerous) or malignant (cancerous) liver tumour,
- if you suffer or have ever suffered, or if it is suspected that you suffer from a malignant sex-hormone dependent tumour such as cancer of the breast or the genital organs,
- if you have any unexplained vaginal bleeding.

**Warnings and precautions**

You must not use hormonal contraceptives of any form (tablet, patch, intrauterine system) while taking ROVULUM.

ROVULUM is NOT a contraceptive. If you want to prevent pregnancy, you should use condoms or other non-hormonal contraceptive precautions.

Take special care with ROVULUM:

- if you have ever had a blood clot (venous thromboembolism) or anyone in your immediate family has had a blood clot at a relatively early age,
- if you have a close relative who has had breast cancer,
- if you have ever suffered from depression,
- if you have high blood pressure or develop high blood pressure while taking ROVULUM,
- if you develop a liver disease while taking ROVULUM. Symptoms may include yellowing of the skin or eyes or itching all over your body. Inform your doctor also if such symptoms occurred during a previous pregnancy,
- if you have diabetes or had diabetes temporarily during previous pregnancy,
- if you have ever had chloasma (golden-brown patches on the skin, particularly of the face); if so, avoid too much exposure to the sun or ultraviolet radiation,
- if you suffer from pain in your lower abdomen (stomach) while taking ROVULUM.

While taking ROVULUM your chance of becoming pregnant is reduced because ROVULUM may affect ovulation.
If you become pregnant while taking ROVULUM you are at a slightly increased risk of having an extrauterine pregnancy (the embryo develops outside the womb). Tell your doctor before you start taking ROVULUM, if you had an extrauterine pregnancy in the past or have an impaired function of the fallopian tubes.

**ROVULUM and serious uterine bleeding**

Uterine bleeding may become worse with the use of ROVULUM. If bleeding is heavy and continuous over time, this may lead to low red blood cell levels (anaemia), which may be severe in some cases. In the event of anaemia, you should discuss with your doctor if you should stop taking ROVULUM.

**ROVULUM and changes in bleeding pattern**

Most women treated with ROVULUM experience changes in their menstrual bleeding pattern (see section 4).

**ROVULUM and blood clots**

There may be an increased risk of a blood clot in the legs (venous thromboembolism) associated with the use of medicines with progestogens like ROVULUM. Blood clots may cause serious permanent disabilities or may even be fatal.

The risk of a venous blood clot increases:

- with increasing age,
- if you are overweight,
- if you or one of your close relatives had a blood clot in the leg (thrombosis), lung (pulmonary embolism) or other organ at a young age,
- if you must have surgery, if you have had a serious accident or if you are immobilized for a long time. It is important to tell your doctor in advance that you are taking ROVULUM as the treatment may have to be stopped. Your doctor will tell you when to start taking ROVULUM again. This is usually about two weeks after you are back on your feet.

ROVULUM is not likely to cause an increased risk of a blood clot in, for example, the blood vessels of the heart (heart attack) or the brain (stroke). However, in women with hypertension (high blood pressure) the risk of a stroke may be enhanced by ROVULUM. Stop taking ROVULUM and contact your doctor immediately if you notice possible signs of a blood clot, such as:

- severe pain and/or swelling in one of your legs;
- sudden severe pain in the chest which may reach the left arm;
- sudden breathlessness;
- sudden cough without an obvious cause;
- any unusual, severe or long-lasting headache or worsening of migraine;
- partial or complete blindness or double vision;
- difficulty in speaking or inability to speak;
- giddiness or fainting;
- weakness, strange feeling, or numbness in any part of the body.

**ROVULUM and cancer**

Breast cancer has been observed slightly more often in women taking hormones compared to those not taking hormones, but it is not known whether this is caused by the treatment. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

Liver tumours have been reported in women taking hormones. Contact your doctor if you have unusually severe stomach pain.

**ROVULUM and osteoporosis (a disease that weakens bones)**

*Changes in bone mineral density (BMD)*

The use of ROVULUM may affect the strength of the bone of adolescents (ages 12 to under 18 years). If you are under 18 your doctor will, therefore, carefully weigh the benefits and risks of using ROVULUM for you as an individual patient, considering possible risk factors for bone loss (osteoporosis).

Your healthcare provider will consider all risks (e.g. family history of bone disease, low weight, smoking, alcohol abuse) when prescribing ROVULUM. Adequate intake of calcium and vitamin D, whether from the diet or from supplements, is important for bone health in women of all ages.

**ROVULUM and psychiatric disorders**

Some women using hormonal medicines, including ROVULUM, 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.

**Children**

ROVULUM is not for use in girls before menarche (first menstrual bleeding).

**Other medicines and ROVULUM**

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

Tell your doctor if you are taking any of the following medicines as they can have influence on the blood levels of ROVULUM and can make it less effective or can cause undesirable effects:

Medicines used for the treatment of:

- epilepsy (e.g. phenytoin, barbiturates, primidone, carbamazepine, oxcarbazepine, topiramate, felbamate),

- tuberculosis (e.g. rifampicin),
- HIV and Hepatitis C Virus infections (so-called protease inhibitors and non-nucleoside reverse transcriptase inhibitors such as ritonavir, nevirapine, efavirenz),
- fungal infections (griseofulvin, ketoconazole, itraconazole, fluconazole, voriconazole),
- antibiotics (e.g. erythromycin, clarithromycin and roxithromycin),
- antacids such as cimetidine,
- blood pressure medicine such as verapamil and diltiazem,
- antidepressants (e.g nefazodone, fluvoxamine, fluoxetine),
- the herbal remedy St. John's wort.

Laboratory tests

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

**ROVULUM with food and drink**

During ROVULUM treatment, you should avoid drinking grapefruit juice, because this may increase the levels of ROVULUM in your blood. This may increase the risk of getting side effects.

**Pregnancy and breastfeeding**

You should not take ROVULUM if you are pregnant or breastfeeding your baby.

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 provider for advice before taking this medicine.

**Driving and using machines**

ROVULUM is not expected to influence your ability to drive.

It is not always possible to predict to what extent ROVULUM may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which ROVULUM affects you (see section 4).

**ROVULUM contains lactose monohydrate**

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

## 3. How to take ROVULUM

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

Always take ROVULUM exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The usual dose of ROVULUM is one tablet every day, preferably at the same time with some liquid as needed. When a pack is finished the next one should be started without interruption. Continue to take the tablets also on days of menstrual bleeding.

Your doctor will tell you how long your treatment with ROVULUM will last. Do not stop treatment early. If you have the impression that the effect of ROVULUM is too strong or too weak, tell your doctor or pharmacist

**If you take more ROVULUM 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.

**If you forget to take ROVULUM**

Do not take a double dose to make up for forgotten individual doses.

## 4. Possible side effects

ROVULUM can have side effects.

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

If any of the following happens, stop taking ROVULUM and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and 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 reaction to ROVULUM. 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:

- Chest pain (angina), changes in the way your heart beats (heart palpitations), for example, if you notice it beating faster,
- difficulty in breathing,
- breast cancers,
- blood clots that can lead to a stroke,
- blood disorders that lead to tiredness,
- suicidal behaviour or thoughts of harming or killing yourself.

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:*

- Weight gain,
- depressed mood, problems sleeping, nervousness, loss of interest in sex, or changed mood,
- headache or migraine,
- nausea, abdominal pain, wind, swollen tummy or vomiting,
- acne or hair loss,
- back pain,
- breast discomfort, ovarian cyst or hot flushes,
- uterine/vaginal bleeding including spotting,
- weakness or irritability.

*Less frequent side effects:*

- Anaemia,
- weight loss or increase in appetite,
- anxiety, depression or mood swings,
- imbalance in the autonomic nervous system (controls unconscious bodily functions, e.g. perspiration) or disturbed attention,
- dry eye,
- tinnitus (ringing in the ears),
- unspecific circulatory problems,
- low blood pressure,
- shortness of breath,
- diarrhoea, constipation, abdominal discomfort, inflammation of the stomach and intestines (gastrointestinal inflammation),
- inflammation of the gums (gingivitis),

- dry skin, excessive sweating, severe itching of the whole body, male pattern hair growth (hirsutism),
- brittle nails, dandruff, dermatitis, abnormal hair growth, hypersensitive response to light or problems with skin pigmentation,
- pains in your bones, muscle spasms, pains and/or a sensation of heaviness in your arms and hands or legs and feet,
- urinary tract infection,
- vaginal thrush, dryness of the genital area, vaginal discharge, pelvic pain, atrophic inflammation of the genitals with discharge (atrophic vulvovaginitis), or a lump or lumps in the breast,
- swelling due to fluid retention,
- additional side effects in adolescents (ages 12 to under 18 years): loss of bone density.

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 side effects to:

**SAHPRA:** via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications:

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

**Aspen Pharmacare:**

**E-mail:** Drugsafety@aspenpharma.com

**Tel:** 0800 118 088

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

## 5. How to store ROVULUM

Store all medicines out of reach of children.

Store at or below 25 °C.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

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 ROVULUM contains**

The active substance is 2 mg of dienogest.

The other ingredients are cottonseed oil hydrogenated, hydroxypropylcellulose (E463), hypromellose (E464), lactose monohydrate, maize starch, magnesium stearate, povidone, sodium starch glycolate (type A), talc (E553b), titanium dioxide (E171).

Contains sugar: Lactose monohydrate 57,2 mg

**What ROVULUM looks like and contents of the pack**

ROVULUM is a white, round, biconvex film-coated tablet embossed with "2" on one side.

ROVULUM is packed in PVC/PVDC/Aluminium blister strips. The blister strips are packed in printed cartons. Pack size of 28 film-coated tablets.

**Holder of Certificate of Registration**

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

**Hotline:** 0800 122 912

**This leaflet was last revised in**

29 August 2023

**Registration number**

52/21.8.2/0336

**Access to the corresponding Professional Information**

**SAHPRA Repository of Professional Information and Patient Information Leaflets:**

https://www.sahpra.org.za/pi-pil-repository/

**Aspen Pharmacare:**

**E-mail:** Medinfo@aspenpharma.com

**Tel:** 0800 118 088

ZA_ROVUTAB_2308_00