SCHEDULING STATUS

S3

DIENOGEST 2 mg PHARMC tablets

Dienogest

Contains sugar: lactose monohydrate 60,93 mg

Read all of this leaflet carefully before you take DIENOGEST 2 mg PHARMC

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- DIENOGEST 2 mg PHARMC 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 DIENOGEST 2 mg PHARMC is and what it is used for
2. What you need to know before you take DIENOGEST 2 mg PHARMC
3. How to take DIENOGEST 2 mg PHARMC
4. Possible side effects
5. How to store DIENOGEST 2 mg PHARMC
6. Contents of the pack and other information

1. What DIENOGEST 2 mg PHARMC is and what it is used for

DIENOGEST 2 mg PHARMC contains a hormone, the progestogen dienogest. DIENOGEST 2 mg

PHARMC is a hormone preparation indicated for the treatment of the painful symptoms of endometrial lesions (displaced tissue of the lining of the womb). DIENOGEST 2 mg PHARMC tablets cause the shrinking of the endometrial tissue and reduces associated complaints such as pelvic pain and painful monthly bleedings. Safety and efficacy beyond 24 months have not been established.

2. What you need to know before you take DIENOGEST 2 mg PHARMC

Do not take DIENOGEST 2 mg PHARMC:

- if you are hypersensitive (allergic) to dienogest or any of the other ingredients of DIENOGEST 2 mg PHARMC (listed in section 6),
- if you are pregnant or think you might be pregnant,
- if you are breastfeeding,
- if you are suffering from blood clot (thromboembolic disorder) in your veins. Thrombosis is the formation of a blood clot which may block a blood vessel. Thrombosis sometimes occurs in the deep veins of the legs (deep vein thromboembolism). If this blood clot breaks away from the veins where it is formed, it may reach and block arteries of the lungs, causing a so-called “pulmonary embolism”. This may occur for example in the blood vessels of the legs (deep vein thrombosis) and the lungs (pulmonary embolism),
- if you have or have ever had several arterial diseases, including cardiovascular diseases such as a heart attack, stroke or heart diseases which cause reduced blood supply to the heart (angina pectoris),
- if you have diabetes mellitus (a group of diseases that affect how your body uses blood sugar),
- if you suffer or have ever suffered from severe liver disease (as long as your liver function values have not returned to normal). Symptoms of liver diseases may be, for instances, yellowing of the skin and/ or itching of the whole body,
- if you have or have ever had a non-invasive or invasive cancer of the liver,
- if you suffer or have ever suffered from invasive sex hormone-dependent tumour such as cancer of the breast or the genital organs,

- if you have unexplained vaginal bleeding.

Warnings and precautions

You must not use hormonal contraceptives of any form (tablet, patch, intrauterine system) while taking DIENOGEST 2 mg PHARMC.

DIENOGEST 2 mg PHARMC is NOT a contraceptive. If you want to prevent pregnancy, you should use condoms or other non-hormonal contraceptive precautions.

In some situations you need to take special care while taking DIENOGEST 2 mg PHARMC, and your doctor may need to examine you regularly. Tell your doctor if any of the following conditions applies to you:

- 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 DIENOGEST 2 mg PHARMC;
- If you develop a liver disease while taking DIENOGEST 2 mg PHARMC. 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 while taking DIENOGEST 2 mg PHARMC.

While taking DIENOGEST 2 mg PHARMC your chance of becoming pregnant is reduced because DIENOGEST 2 mg PHARMC may affect ovulation.

If you become pregnant while taking DIENOGEST 2 mg PHARMC 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 DIENOGEST 2 mg PHARMC, if you had an extrauterine pregnancy in the past or have an impaired function of the Fallopian tubes.

DIENOGEST 2 mg PHARMC and serious uterine bleeding:

Uterine bleeding, for example in women with a condition where the mucous membrane of your uterus (endometrium) grows into the muscle layer of your uterus, called adenomyosis uteri or benign tumours of the womb sometimes called uterine fibroids (uterine leiomyomata), may become worse with the use of DIENOGEST 2 mg PHARMC. If bleeding is heavy and continuous over time, this may lead to low red blood cell levels (anemia), which may be severe in some cases. In the event of anemia, you should discuss with your doctor if you should stop taking DIENOGEST 2 mg PHARMC.

DIENOGEST 2 mg PHARMC and changes in bleeding pattern:

Most women treated with DIENOGEST 2 mg PHARMC experience changes in their menstrual bleeding pattern (see section 4, Possible side effects).

DIENOGEST 2 mg PHARMC and venous blood clots:

Some studies indicate that there may be a slight, but not statistically significant, increased risk of a blood clot in the legs (venous thromboembolism) associated with the use of preparations with progestagens like DIENOGEST 2 mg PHARMC. Very rarely, 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 using DIENOGEST 2 mg PHARMC as the treatment may have to be stopped. Your doctor will tell you when to start DIENOGEST 2 mg PHARMC again. This is usually about two weeks after you are back on your feet.

DIENOGEST 2 mg PHARMC and arterial blood clots:

There is little evidence for an association between preparations with progestagens like DIENOGEST 2 mg PHARMC and an increased risk of a blood clot in, for example, the bloodvessels of the heart (heart attack) or the brain (stroke). In women with hypertension (high blood pressure) the risk of stroke may be slightly enhanced by these preparations.

The risk of an arterial blood clot increases:

- if you smoke. You are strongly advised to stop smoking when you use DIENOGEST 2 mg PHARMC, especially if you are older than 35 years;
- if you are overweight;
- if one of your close relatives had a heart attack or stroke at a young age;
- if you have high blood pressure.

DIENOGEST 2 mg PHARMC and cancer:

It is not clear from the data currently available whether or not DIENOGEST 2 mg PHARMC increases the risk of breast 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. For example, it may be that more tumours are detected and detected earlier in women taking hormones because they are examined by their doctor more often. The occurrence of breast tumours becomes gradually less after stopping the hormone treatment. It is important to regularly check your breasts and you should contact your doctor if you feel any lump.

In rare cases, benign liver tumours, and in even fewer cases malignant liver tumours have been reported in women taking hormones. Contact your doctor if you have unusually severe stomach pain.

DIENOGEST 2 mg PHARMC and osteoporosis:

Changes in bone mineral density (BMD)

The use of DIENOGEST 2 mg PHARMC may affect the strength of the bone of adolescents (12 to under 18 years). If you are under 18 your doctor will, therefore, carefully weigh the benefits and risks of using DIENOGEST 2 mg PHARMC for you as an individual patient, taking into account possible risk factors for bone loss (osteoporosis).

If you use DIENOGEST 2 mg PHARMC, it will help your bones if you have an adequate intake of calcium and vitamin D either via your food or via supplements.

If you have an increased risk of getting osteoporosis (weakening of bones due to loss of bone minerals), your doctor will carefully weigh the risks and benefits of treatment with DIENOGEST 2 mg PHARMC because DIENOGEST 2 mg PHARMC has a moderate suppressing effect on the production of oestrogen (another type of female hormone) by your body.

Children and adolescents

DIENOGEST 2 mg PHARMC is not for use in girls before menarche (first menstrual bleeding). The use of DIENOGEST 2 mg PHARMC may affect the strength of the bone of adolescents (12 to under 18 years). If you are under 18 your doctor will, therefore, carefully weigh the benefits and risks of using DIENOGEST 2 mg PHARMC for you as an individual patient, taking into account possible risk factors for bone loss (osteoporosis).

Other medicines and DIENOGEST 2 mg PHARMC

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

The following may reduce the effects of DIENOGEST 2 mg PHARMC:

- Medicines used for the treatment of:
  - Epilepsy (e.g. phenytoin, barbiturates, primidone, carbamazepine, oxcarbamazepine, topiramate, felbamate)

- Tuberculosis (e.g. rifampicin)
- HIV infections: non-nucleoside reverse transcriptase inhibitors (e.g. nevirapine)
- Other infections (antibiotics such as griseofulvin)
- Herbal remedy St. John's wort (for depression)

The following may increase the levels of DIENOGEST 2 mg PHARMC in your blood:

➢ Medicines such as:

- Medicines used to treat fungal infections (e.g., ketoconazole, itraconazole, fluconazole)
- Antibiotics (erythromycin, clarithromycin and roxithromycin)
- Medicines used for depression (e.g. nefazodone, fluvoxamine, fluoxetine)
- Antacids (e.g. cimetidine)
- Blood pressure medication (e.g. diltiazem, verapamil)
- Protease inhibitors for HIV infections (e.g. ritonavir, saquinavir, indinavir or nelfinavir).

Laboratory tests

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

Pregnancy and breastfeeding

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 health care provider for advice before you take DIENOGEST 2 mg PHARMC.

Do not take DIENOGEST 2 mg PHARMC if you are pregnant or breastfeeding.

Taking DIENOGEST 2 mg PHARMC with food and drink

A standardised high fat meal does not affect the levels of dienogest

2 mg in your body. During DIENOGEST 2 mg PHARMC treatment, you should avoid drinking grapefruit juice, because this may increase the levels of DIENOGEST 2 mg PHARMC in your blood. This may increase the risk of getting side effects**.**

Driving and using machines

No effects on the ability to drive and use machines have been observed in users of DIENOGEST 2 mg PHARMC.

DIENOGEST 2 mg PHARMC contains lactose

DIENOGEST 2 mg PHARMC contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus. Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take DIENOGEST 2 mg PHARMC.

3. How to take DIENOGEST 2 mg PHARMC

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

Always take DIENOGEST 2 mg PHARMC exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

The following statement applies to DIENOGEST 2 mg PHARMC unless otherwise prescribed by your doctor. Please observe these instructions for use, otherwise you will not fully benefit from DIENOGEST 2 mg PHARMC.

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

The dosage of DIENOGEST 2 mg PHARMC is one tablet daily without any break, taken preferably at the same time each day with some liquid as needed. Tablets must be taken throughout 28 days without regard to bleeding. This means that after the first pack has been finished, the next should be started without interruptions.

If you take more DIENOGEST 2 mg PHARMC than you should

You should not take more than your doctor tells you to. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take DIENOGEST 2 mg PHARMC /If you suffer from vomiting and/ or diarrhoea:

The efficacy of DIENOGEST 2 mg PHARMC may be reduced in the event of missed tablets, vomiting and/ or diarrhoea (if occurring within 3 to 4 hours after tablet taking). In the event of missed tablet(s), you should take one tablet only, as soon as you remember, and should then continue the next day to take the tablet at your usual time. A tablet not absorbed due to vomiting or diarrhoea should likewise be replaced by one tablet. Do not take a double dose to make up for forgotten individual doses.

If you stop taking DIENOGEST 2 mg PHARMC:

If you stop taking DIENOGEST 2 mg PHARMC, your original endometriosis complaints may re-occur.

4. Possible side effects

DIENOGEST 2 mg PHARMC can have side effects.

Not all side effects reported for DIENOGEST 2 mg PHARMC are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking DIENOGEST 2 mg PHARMC, please consult your health care provider for advice.

If any of the following happens, stop taking DIENOGEST 2 mg PHARMC 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 DIENOGEST 2 mg PHARMC. You may need urgent medical attention or hospitalisation.

Stop taking DIENOGEST 2 mg PHARMC and see your doctor immediately if you notice possible

signs of thrombosis which include:

- breathlessness;
- an unusual cough;
- severe pain in the chest which may reach the left arm;
- any unusual, severe or prolonged headache or migraine attack;
- partial or complete loss of vision, or double vision;
- slurring or speech disability;
- sudden changes to your hearing, sense of smell or taste;
- dizziness or fainting;
- weakness or numbness in any part of your body;
- severe pain in your abdomen;
- severe pain or swelling in either of your legs.

It is also important to immediately tell your doctor if you notice any of the following:

- a lump in your breast;
- unusual, heavy vaginal bleeding;
- other abdominal complaints that are different to the symptoms you commonly experience from your endometriosis.

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

Tell your doctor if you notice any of the following:

Frequent

- weight gain;
- depressed mood, problems sleeping, nervousness, loss on 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 (asthenic conditions) or irritability.

Less frequent

- anaemia;
- weight loss or increased appetite;
- anxiety, depression or mood swings;
- imbalance in the autonomic nervous system (controls unconscious bodily functions e.g. perspiration) or disturbed attention;
- dry eyes;
- tinnitus;
- unspecified circulatory problems or palpitations (e.g. transient feeling of fatigue or dizziness);
- 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, itching of the whole body, male pattern hair growth (hirsutism), brittle nails, dandruff, dermatitis, abnormal hair growth, hypersensitive response to light or problem with skin pigmentation (e.g. patches of darker pigmentation in the facial area);
- pain in your bones, muscle spasm, pains and/ or 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 (breast mass, fibrocystic breast disease, breas induration);
- swelling due to fluid retention.

Additional side effects in adolescents (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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. In addition, side effects can also be reported to info@pharmacorp.co.za.

By reporting side effects, you can help provide more information on the safety of DIENOGEST 2 mg PHARMC.

5. How to store DIENOGEST 2 mg PHARMC

Store all medicines out of reach of children.

- Store at or below 25 °C.
- Store in the original package in order to protect from light.
- Do not use after the expiry date stated on the carton or 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 DIENOGEST 2 mg PHARMC contains

- The active substance is dienogest.

Each DIENOGEST 2 mg PHARMC tablet contains 2 mg of dienogest.

Contains sugar: lactose monohydrate 60,93 mg per tablet.

- The other ingredients are lactose monohydrate, maize starch, povidone K-30 and vegetable magnesium stearate.

What DIENOGEST 2 mg PHARMC looks like and contents of the pack

DIENOGEST 2 mg PHARMC is a white, round, biconvex and plain tablet, with a diameter of 5 mm approximately and thickness about 3 mm.

DIENOGEST 2 mg PHARMC is packaged in PVC/PVDC/aluminium blisters. Aluminium foil is a foil of aluminium push-through with a dull side lacquered, and a bright side heat sealable lacquered for sealing to PVC. One blister calendar pack with 28 tablets, is packed into a carton box.

Holder of Certificate of Registration

PHARMACORP (PTY) LTD

29 Victoria Link

Route 21 Corporate Park

Irene, 0178

RSA

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Access to the corresponding Professional Information

(and the translated Patient Information Leaflet)

www.pharmacorp.co.za