APPROVED PATIENT INFORMATION LEAFLET

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

DIENOGEST 2 mg DYNA tablet

Dienogest

DIENOGEST 2 mg DYNA contains sugar (lactose monohydrate 60,93 mg)

Read all of this leaflet carefully before you start taking DIENOGEST 2 mg DYNA

- 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.
- DIENOGEST 2 mg DYNA 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 DYNA is and what it is used for
2. What you need to know before you take DIENOGEST 2 mg DYNA
3. How to take DIENOGEST 2 mg DYNA
4. Possible side effects
5. How to store DIENOGEST 2 mg DYNA

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6. Contents of the pack and other information

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

DIENOGEST 2 mg DYNA contains a hormone, the progestogen dienogest, which is a hormone preparation indicated for the long-term treatment of endometriosis (painful symptoms of displaced tissue of the lining of the womb) in adolescents after their first menstrual bleeding from 12 years of age onward and in adults. DIENOGEST 2 mg DYNA tablets cause the shrinking of the endometrial tissue and reduces associated complaints such as pelvic pain and painful monthly bleedings.

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

Do not take DIENOGEST 2 mg DYNA:

- if you are hypersensitive (allergic) to dienogest, or to any of the other ingredients of DIENOGEST 2 mg DYNA (see section 6)
- if your blood can form blood clots easily (thrombophilia) or if you suffer from blood clot(s) (thromboembolic disorder) in your veins. . If a 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 ever had several arterial diseases, including cardiovascular diseases such as a heart attack, stroke (such as transient ischaemic attack or small

reversible stroke) or heart diseases which cause reduced blood supply to the heart (angina pectoris)

- if you have diabetes mellitus with blood vessel damage
- if you suffer or have ever suffered from any liver disease (and 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.

If any of these conditions appear for the first time while taking DIENOGEST 2 mg DYNA, stop taking it at once and consult your doctor.

Warnings and precautions

Take special care with DIENOGEST 2 mg DYNA:

Because DIENOGEST 2 mg DYNA is not supposed to be used in pregnancy, you are advised to use non-hormonal method for contraception (barrier contraception e.g. condom) to prevent an unwanted pregnancy. You must not use sex-hormone containing contraceptives of any form (tablet, patch, intrauterine system) while taking DIENOGEST 2 mg DYNA. Do not use the rhythm or temperature methods. These methods can be unreliable because DIENOGEST 2 mg DYNA alters the usual changes in temperature and cervical mucus that occur during the menstrual cycle.

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If you become pregnant during the use of DIENOGEST 2 mg DYNA, there is a higher likelihood of an extrauterine pregnancy (the embryo develops outside the womb). Tell your doctor before you start taking DIENOGEST 2 mg DYNA, if you had an extrauterine pregnancy in the past or have an impaired function of the fallopian tube.

Tell your doctor before taking DIENOGEST 2 mg DYNA:

- if you have high blood pressure or develop high blood pressure while taking DIENOGEST 2 mg DYNA
- if you have ever had a blood clot (venous thromboembolism) or anyone in your immediate family
- if you are overweight
- if you have a close relative who has had breast cancer. There is an increased risk of break cancer being diagnosed in patients taking DIENOGEST 2 mg DYNA. Cases of benign liver tumours, and even more rarely malignant liver tumours have been reported in patients taking hormonal medicines such as DIENOGEST 2 mg DYNA, in very rare cases these tumours have led to life-threatening intra-abdominal haemorrhaging
- if you have a liver disease or had symptoms of liver disease that occurred during a previous pregnancy. These symptoms may include yellowing of the skin or eyes or itching all over your body
- if you have ever suffered from depression
- if you have diabetes or had diabetes temporarily during previous pregnancy

- if you have or have had chloasma (yellowish-brown pigmentation patches on the skin, particularly of the face). If so, avoid too much exposure to the sun or ultraviolet radiation.
- if you have inherited genetic mutations: BRCA1 and BRCA 2 genes, as you have a higher risk of developing cancer
- 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

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 DYNA. 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 DIENOGEST 2 mg DYNA.

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DIENOGEST 2 mg DYNA and thrombosis

The risk of having deep venous thrombosis is temporarily increased as a result of an operation or immobilisation (for example, when you have your leg or legs in plaster or splints). In women who use DIENOGEST 2 mg DYNA the risk may be yet higher. Tell your doctor you are using DIENOGEST 2 mg DYNA well in advance of any expected hospitalisation or surgery. Your doctor may tell you to stop taking DIENOGEST 2 mg DYNA several weeks before surgery or at the time of immobilisation. Your doctor will also tell you when you can start taking DIENOGEST 2 mg DYNA again after you are back on your feet.

If you have just given birth, you are at an increased risk of blood clots. You should ask your doctor how soon after delivery you can start taking DIENOGEST 2 mg DYNA.

DIENOGEST 2 mg DYNA and cancer

DIENOGEST 2 mg DYNA contains an dienogest, which may increase the risk of developing breast cancer in women between 40 – 59 years, during long-term use. Breast cancer has been diagnosed slightly more often in women who use hormones, such as DIENOGEST 2 mg DYNA, than in women of the same age who do not use hormones. This slight increase in the numbers of breast cancer diagnoses gradually disappears during the course of the 10 years after stopping use of the hormones.

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 DIENOGEST 2 mg DYNA).

In rare cases benign liver tumours, and even more rarely, malignant liver tumours have been reported. These tumours may lead to internal bleeding. Contact your doctor immediately if you have severe pain in your abdomen.

Children and adolescents

DIENOGEST 2 mg DYNA should not be given to children under the age of 12 years and before their first menstrual bleeding.

Changes in bone mineral density (BMD)

The use of DIENOGEST 2 mg DYNA may affect the strength of the bone of adolescents (12 to under 18 years). If you have an increased risk of getting osteoporosis (weakening of bones due to loss of bone minerals), your doctor will decide whether to prescribe you DIENOGEST 2 mg DYNA or not.

If you are a woman taking DIENOGEST 2 mg DYNA, you are advised to increase your daily calcium and vitamin D intake during therapy.

Other medicines and DIENOGEST 2 mg DYNA

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

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

- medicines used for the treatment of:
    - epilepsy (e.g. phenytoin, barbiturates, primidone, carbamazepine,

oxcarbamazepine, topiramate, felbamate)

- tuberculosis (e.g. rifampicin)
- other infections (antifungal such as griseofulvin)

- herbal remedy St. John's wort.

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

- medicines used to treat fungal infections (e.g., ketoconazole, itraconazole, fluconazole, voriconazole)
- antibiotics (erythromycin, clarithromycin)
- blood pressure medication (e.g. diltiazem, verapamil)
- nefazodone, fluvoxamine or fluoxetine (used to treat depression.

The following may increase or decrease the levels of DIENOGEST 2 mg DYNA in your blood

- protease inhibitors for HIV infections (e.g. ritonavir, saquinavir, indinavir or nelfinavir).

DIENOGEST 2 mg DYNA may interfere with the results of certain laboratory tests, it is therefore important that you inform your doctor or the laboratory that you are taking DIENOGEST 2 mg DYNA in the event you require blood tests

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DIENOGEST 2 mg DYNA with food and drink

DIENOGEST 2 mg DYNA can be taken with or without food.

Grapefruit juice may increase the levels of DIENOGEST 2 mg DYNA in your blood and should be avoided.

Pregnancy, breastfeeding, and fertility

If you are pregnant, breastfeeding or think you may be pregnant or planning to have a baby, please consult your doctor, pharmacist, or other healthcare provider for advice before using DIENOGEST 2 mg DYNA.

DIENOGEST 2 mg DYNA should not be used during pregnancy because there is no need to treat endometriosis during pregnancy. If you fall pregnant while taking DIENOGEST 2 mg DYNA, stop taking the medicine immediately and notify your healthcare provider.

Treatment with DIENOGEST 2 mg DYNA is not recommended during breastfeeding.

DIENOGEST 2 mg DYNA is not a contraceptive. If contraception is required, non-hormonal methods should be used (i.e. condoms).

Driving and using machines

DIENOGEST 2 mg DYNA is not expected to affect your ability to drive or use machines.

It is not always possible to predict to what extent DIENOGEST 2 mg DYNA 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 DIENOGEST 2 mg DYNA affects you.

DIENOGEST 2 mg DYNA contains lactose

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

3. How to take DIENOGEST 2 mg DYNA

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

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 DYNA 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.

Your doctor will tell you how long your treatment with DIENOGEST 2 mg DYNA will last. Do not stop treatment early because your original endometriosis complaints may re-occur. If you have the impression that the effect of DIENOGEST 2 mg DYNA is too strong or too weak, tell your doctor or pharmacist.

If you take more DIENOGEST 2 mg DYNA 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 DIENOGEST 2 mg DYNA

The efficacy of DIENOGEST 2 mg DYNA 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 DYNA

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

4. Possible side effects

DIENOGEST 2 mg DYNA may have side effects.

Not all side effects reported for DIENOGEST 2 mg DYNA are included in this leaflet.

Should your general health worsen, or if you experience any untoward effects while using DIENOGEST 2 mg DYNA, please consult your healthcare provider for advice.

If any of the following happens, stop using DIENOGEST 2 mg DYNA 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 DIENOGEST 2 mg DYNA. 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:

- possible signs of thrombosis (occurs when blood clots block veins or arteries) 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.
- unspecified circulatory problems or palpitations (e.g. transient feeling of fatigue or dizziness).

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
- feeling depressed, problems sleeping, nervousness, loss of interest in sex, changed mood, irritability
- headache, migraine
- nausea, abdominal pain, farting, swollen tummy or vomiting
- acne, hair loss
- back pain
- breast discomfort, ovarian cyst, hot flushes, vaginal bleeding or spotting
- lack of strength, feeling weak.

Less frequent side effects:

- 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 (ringing or buzzing in the ears)
- low blood pressure
- shortness of breath
- diarrhoea, constipation, stomach ache, 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, breast induration)

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. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.By reporting side effects, you can help provide more information on the safety of DIENOGEST 2 mg DYNA. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

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5. How to store DIENOGEST 2 mg DYNA

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. 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 DYNA contains

Each tablet contains 2 mg dienogest.

The other ingredients are:

Lactose monohydrate, maize starch, povidone K-30, vegetable magnesium stearate.

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

DIENOGEST 2 mg DYNA tablets are white, round, biconvex and plain, with a diameter of 5 mm approximately and thickness about 3 mm.

DIENOGEST 2 mg DYNA tablets are available in Aluminium-PVC/PVDC blister strips.

Pack sizes 28 tablets in a blister, such that one blister is packed into a printed outer carton.

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