Patient Information Leaflet

SCHEDULING STATUS

S3

DIENTERNA 2, 2 mg, tablets

Dienogest

Read all of this leaflet carefully before you start taking DIENTERNA 2

- 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.
- DIENTERNA 2 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 DIENTERNA 2 is and what it is used for

DIENTERNA 2 is a hormone preparation indicated for the treatment of endometriosis (painful disorder in which tissue similar to the tissue that normally lines the inside of your womb grows outside your womb). DIENTERNA 2 contains a hormone, the progestogen, dienogest.

DIENTERNA 2 tablets cause the shrinking of the endometrial tissue (tissue of the womb) and

reduces symptoms associated with endometriosis such as pelvic pain and painful monthly bleedings.

2. What you need to know before you use DIENTERNA 2

Do not take DIENTERNA 2

- If you are allergic to dienogest or to any of the components listed in section 6.
- If you are pregnant or think you might be pregnant (see “Pregnancy and breastfeeding”).
- If you are breastfeeding (see “Pregnancy and breastfeeding”).
- If you are suffering from or have a history of having blood clots (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 had arterial diseases, including cardiovascular diseases such as a heart attack, stroke or heart diseases which cause reduced blood supply to the heart (ischaemic heart disease).
- If you have diabetes mellitus (disease causing high blood sugar) and associated diseases of blood vessels.
- If you suffer or have ever suffered from severe liver disease (this applies for as long as it takes for your liver function values to return to normal).
- If you have or ever had a liver cancer.
- If you suffer from or if it is suspected that you have a sex hormone-dependent malignant (harmful) cancer of the breast or the sex organs.
- If you have unexplained vaginal bleeding.

Warnings and precautions

Talk to your doctor or health care provider before using DIENTERNA 2.

Take special care with DIENTERNA 2:

- If you have or have had serious uterine bleeding (bleeding from the womb/vaginal bleeding) as DIENTERNA 2 may aggravate (worsen) the bleeding resulting in anaemia (low red blood cells).
- DIENTERNA 2 may change your menstrual bleeding pattern (monthly period).
- If you have hypertension (high blood pressure) as DIENTERNA 2 may increase the risk of stroke (event that occurs when part of the brain loses its blood supply and stops working due to bleeding or a clot in a blood vessel).
- Progestogen-only medicines such as DIENTERNA 2 may increase the risk of blood clots. If you planning to go for surgery that will render you immobile (incapable of moving or being moved) your doctor might want to discontinue treatment four weeks in advance until two weeks after remobilization (when you are able to move around or being moved around).
- Liver tumours have been reported in users of hormonal medicines such as in DIENTERNA 2. Therefore, it is important to notify your doctor if you experience severe upper abdominal pain.
- If you are at increased risk of developing osteoporosis (disease causing bones to become weak and brittle).
- If you suffer from depression.
- If you experience a recurrence of cholestatic jaundice (condition in which the flow of bile from the liver stops or slows) and/or pruritus (uncomfortable, irritating sensation that creates an urge to scratch that can involve any part of the body) which occurred first during pregnancy or previous use of sex hormones.
- If you have diabetes (high blood sugar) or developed diabetes during pregnancy (gestational diabetes mellitus) as dienogest may affect your blood sugar levels.
- If you have or have had chloasma (formation of brownish pigmentation of the face, often

occurring in pregnancy) avoid exposure to the sun or ultraviolet radiation whilst taking DIENTERNA 2.

- If you have a history of extrauterine pregnancy (a pregnancy in which the fertilised egg implants outside the uterus/womb).
- Ovarian cysts (fluid filled sacks in the ovary) may occur during the use of DIENTERNA 2. They are mostly asymptomatic, although some may be accompanied by pelvic pain. If you experience pain in the pelvis contact your doctor.
- DIENTERNA 2 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.

Other medicines and DIENTERNA 2

Always tell your health care provider if you are taking any other medicine.
(This includes all complementary or traditional medicines.)
Some medicines may increase or decrease the effects of DIENTERNA 2 and your doctor may wish to monitor you carefully if you are taking these medicines.

- Enzyme inducing mediation (such as phenytoin, barbiturates, primidone, carbamazepine, rifampicin, oxcarbazepine, topiramate, felbamate, griseofulvin, nevirapine and products containing St. John's wort) may stop DIENTERNA 2 from working properly.
- Enzyme inhibiting medication like azole antifungals (e.g. ketoconazole, itraconazole, fluconazole), cimetidine, verapamil, macrolides (e.g. erythromycin, clarithromycin and roxithromycin), diltiazem, protease inhibitors (e.g. ritonavir, saquinavir, indinavir, nelfinavir), antidepressants (e.g. nefazodone, fluvoxamine, fluoxetine) may increase the levels of DIENTERNA 2 in your blood and result in undesirable effects / side effects.

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 taking this medicine.

Pregnancy

Do not use DIENTERNA 2 if you are pregnant.

Breastfeeding

Do not use DIENTERNA 2 if you are breastfeeding.

Driving and using machines

DIENTERNA 2 has no influence on the ability to drive and use machines. However, it is not always possible to predict to what extent DIENTERNA 2 may interfere with your daily activities. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which DIENTERNA 2 affects them.

DIENTERNA 2 contains lactose

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

3. How to use DIENTERNA 2

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

Always use DIENTERNA 2 exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Tablet-taking from the very first pack must start on day one of the menstrual cycle (i.e. the first day of menstrual bleeding/period).

The dosage of DIENTERNA 2 is one tablet daily without any break, taken preferably at the same time each day. 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.

You can take DIENTERNA 2 with or without food and with some liquid as needed.

Your doctor will tell you how long your treatment with DIENTERNA 2 will last. Do not stop treatment early without discussing it with your doctor. If you have the impression that the effect of DIENTERNA 2 is too strong or too weak, tell your doctor or pharmacist.

If you use more DIENTERNA 2 than you should

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 / missed a dose of DIENTERNA 2

If you forget to take your tablets or missed a dose, DIENTERNA 2 may not work properly and you may not receive the full benefit from it.

If you missed a dose(s), take one tablet as soon as you remember and continue the next day to take the tablet at your usual time. Do not take a double dose to make up for forgotten individual doses.

A tablet not absorbed due to vomiting or diarrhoea should likewise be replaced by one tablet.

If you stop taking/using DIENTERNA 2

Don’t stop taking DIENTERNA 2 without talking to your doctor first.

4. Possible side effects

DIENTERNA 2 can have side effects.

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

You may experience changes in your bleeding patterns (menstrual cycle), such as infrequent or frequent bleeding, irregular bleeding, prolonged bleeding, or your periods may stop completely.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Weight gain.
- Depressed mood, problems sleeping, nervousness, decreased sex drive and mood changes.
- Headaches and migraine (intense headaches often accompanied by nausea and sensitivity to light and sound).
- Nausea, stomach pain, gassiness, bloating and vomiting.
- Acne and hair loss.
- Back pain.
- Breast discomfort, ovarian cyst (fluid filled sack in or on the surface of an ovary that may cause menstrual irregularities or pain), hot flushes and vaginal bleeding.
- Asthenic conditions, irritability.

Less frequent side effects:

- Anaemia (low red blood cell count).

- Weight loss or increased appetite.
- Anxiety, depression, mood swings.
- Autonomic nervous system Imbalance (condition affecting the functioning of the heart, bladder, intestines, sweat glands, pupils, and blood vessels), trouble with attention.
- Dry eyes.
- Tinnitus (ringing or buzzing noise in one or both ears that may be constant or come and go).
- Undetermined circulatory system (blood vessel system) disorder/sickness and rapid and irregular heartbeat (palpitations).
- Low blood pressure (hypotension).
- Difficulty breathing (dyspnoea).
- Diarrhoea, constipation, abdominal discomfort such as stomach pain), gastrointestinal inflammation (inflammation of the digestive system including stomach, intestines), and inflammation of the gums (gingivitis).
- Dry skin, excessive sweating, itchy skin, hirsutism (unwanted male-pattern hair growth on a woman's face, chest and back), breaking nails, dry and flaking scalp (dandruff), skin rash, abnormal hair growth, light sensitivity reaction, pigmentation disorder (affecting skin colour, i.e. development of blotchy, darker or lighter skin or patches of skin).
- Bone pain, muscle cramp, pain in extremity (such as arms, hands legs and feet), heaviness in extremities.
- Urinary tract infection (i.e. kidney-, bladder infection, etc.).
- Vaginal candidiasis (thrush), vaginal dryness or discharge, pain in pelvis, atrophic vulvovaginitis (thinning, drying and inflammation of the vaginal walls), breast mass (lump), fibrocystic breast diseases (fluid filled sacks or scar-like tissue developing in breast causing lumpy or tender breasts), breast hardening.
- Oedema (swelling caused by the accumulation of fluid in a part of the body).

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 **6.04 Adverse Drug Reaction Reporting Form**, found online under SAHPRA"s publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of DIENTERNA 2.

5. How to store DIENTERNA 2

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original packaging to protect from light.

Do not use after the expiry date stated on the blister pack and 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 DIENTERNA 2 contains

The active substance is dienogest.

Each tablet contains 2 mg dienogest.

The other ingredients are: Crospovidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, potato starch, povidone and talc.

What DIENTERNA 2 looks like and contents of the pack

DIENTERNA 2 is white to off-white, round, flat faced bevelled edge tablets debossed with “NC” on one side and “22” on other side.

The tablets are contained in green PVC-PVDC blister packs with
aluminium foil lidding in a cardboard carton. They are supplied in a blister pack containing 14 tablets.

Boxes contain 28, 84 or 168 tablets.

Not all pack sizes may be marketed

Holder of Certificate of Registration

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