PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

DIENOGEST ADCO 2 mg tablets

Dienogest

DIENOGEST ADCO contains 62,81 mg lactose monohydrate per tablet

Read all of this leaflet carefully before you start taking DIENOGEST ADCO

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor, pharmacist, nurse or other healthcare provider.
- DIENOGEST ADCO 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 ADCO is and what it is used for

DIENOGEST ADCO contains a hormone, the progestogen dienogest.

DIENOGEST ADCO is a preparation for the treatment of endometriosis (painful symptoms in which the lining of the womb grows outside the womb).

2. What you need to know before you take DIENOGEST ADCO

Do not take DIENOGEST ADCO:

- if you are hypersensitive (allergic) to dienogest or any of the other ingredients of DIENOGEST ADCO (listed in section 6)
- if you are pregnant or suspect pregnancy
- if you are breastfeeding your baby
- if you are suffering from a blood clot (thromboembolic disorder) in your veins. This may occur, for example, in the blood vessels of the legs (deep vein thrombosis) or the lungs (pulmonary embolism). See also "DIENOGEST ADCO and venous blood clots" below
- 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). See also "DIENOGEST ADCO and arterial blood clots" below
- 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 or malignant 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

Take special care with DIENOGEST ADCO:

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

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

Tell your doctor if any of the following conditions applies to you:

- if you have conditions of the uterus, these conditions may cause your menstrual bleeding (period) to be heavier than usual and continue for longer than usual
- 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 are overweight
- if you become immobile due to any reason, the use of DIENOGEST ADCO should be stopped. Talk to your doctor about this before you stop taking DIENOGEST ADCO
- if you have to go for surgery, treatment with DIENOGEST ADCO should be stopped 4 weeks before surgery. Your doctor will tell you when you can start taking DIENOGEST ADCO again
- if you experience symptoms such as pain and swelling in one leg, chest pain or numbness on one side of your body talk to your doctor immediately. These symptoms may be an indication of a blood clot and treatment with DIENOGEST ADCO should be stopped immediately
- it is important to self-examine your breasts on a regularly basis for possible lumps or swelling. If you feeling anything unusual during your self-examination please contact your doctor immediately
- if you experience upper stomach pain, yellowing of the whites of the eyes and skin, nausea (being sick), vomiting (feeling sick), chest pain, shortness of breath, blood in your urine, contact your doctor immediately

- if you have a family history or if you have been diagnosed with osteoporosis (a condition in which the bones become brittle and fragile from loss of tissue, typically as a result of hormonal changes or deficiency of calcium or vitamin D)
- if you have ever suffered from depression
- if you have high blood pressure or develop high blood pressure while taking DIENOGEST ADCO
- if you develop a liver disease while taking DIENOGEST ADCO. Symptoms may include yellowing of the skin or eyes or itching all over your body
- 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 while taking DIENOGEST ADCO
- if you become pregnant while taking DIENOGEST ADCO, consult your doctor immediately
- if you suffer from pain in your lower abdomen, breast tenderness, changes in your menstrual cycle (period) while taking DIENOGEST ADCO, these may be symptoms of ovarian cysts (a solid or fluid-filled sac or pocket (cyst) within or on the surface of an ovary

Other medicines and DIENOGEST ADCO

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

Some medicines can have an influence on the blood levels of DIENOGEST ADCO and can make it less effective or can cause undesirable effects.

These includes 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)
- the herbal remedy St. John's wort.
- fungal infections (griseofulvin, ketoconazole)

Laboratory tests

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

DIENOGEST ADCO with food and drink

A high fat meal did not affect DIENOGEST ADCO bioavailability. DIENOGEST ADCO can be taken with or without a meal.

Pregnancy, breastfeeding and fertility

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 DIENOGEST ADCO.

Do not take DIENOGEST ADCO if you are pregnant or when breastfeeding your baby.

Women of childbearing potential / Contraception in males and females

If contraception is required a non-hormonal method should be used (e.g. barrier method).

Your menstrual cycle (period) will return to normal within 2 months after stopping treatment with DIENOGEST ADCO.

Fertility

Based on available data, ovulation is inhibited in the majority of patients during treatment.

Driving and using machines

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

It is not always possible to predict to what extent DIENOGEST ADCO may interfere with your daily activities. You should ensure that you do not engage in the driving a vehicle or use machines until you are aware of the measure to which DIENOGEST ADCO affects you.

DIENOGEST ADCO contains lactose monohydrate

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

Children and adolescents

DIENOGEST ADCO is not for use in girls before menarche (first menstrual bleeding). The use of DIENOGEST ADCO 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 ADCO for you as an individual patient, taking into account possible risk factors for bone loss (osteoporosis).

3. How to take DIENOGEST ADCO

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

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

You can start treatment with DIENOGEST ADCO on day one of your natural cycle.

Adults: take 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.

If you take more DIENOGEST ADCO 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 a dose of DIENOGEST ADCO

If you vomit within 3-4 hours of taking DIENOGEST ADCO or you have severe diarrhoea, there is a risk that the active substance in the tablet will not be taken up by your body. The situation is almost the same as forgetting a tablet. After vomiting or diarrhoea within 3-4 hours of taking DIENOGEST ADCO, you should take another tablet as soon as possible.

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

If you stop taking DIENOGEST ADCO

Do not stop taking DIENOGEST ADCO, unless your doctor has instructed you to do so. If you stop taking DIENOGEST ADCO, your original endometriosis symptoms may return.

4. Possible side effects

DIENOGEST ADCO can have side effects.

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

If any of the following happens, stop taking DIENOGEST ADCO 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,
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to DIENOGEST ADCO. 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:

Less frequent:

- changes in the way your heart beats, for example, if you notice it beating faster
- shortness of breath, difficulty breathing
- a frequent or intense urge to pee, even though little comes out when you do, burning when you pee, strange-smelling pee, fever, feeling tired, pain in your lower back.

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

Tell your doctor if you notice any of the following:

Frequent:

- weight gain
- feeling depressed and/or nervous, sleeping problems
- changes in your mood, loss of sex drive
- headache, migraine (throbbing headache usually on one side of your head with sensitivity to light and sound, nausea and vomiting)

- nausea (feeling sick), stomach pain, flatulence (passing wind), bloating and swelling in the belly area, vomiting (being sick)
- acne, hair loss (temporarily)
- back pain
- breast tenderness, pelvic and lower back pain, hot flushes, menstrual bleeding between your periods (spotting)
- chronic tiredness, irritability.

Less frequent:

- dizziness
- weight loss, increased appetite
- feeling anxious, mood swings
- sweating abnormalities, which could alternate between sweating too much and not sweating enough
- high activity level with a short attention span
- dry eyes, tinnitus (ringing in the ears)
- low blood pressure (feeling lightheaded)
- diarrhoea (loose stool), constipation
- swollen, puffy, dark red, sensitive gums
- dry, itchy skin
- abnormal growth of hair on a woman's face and body
- nail disorders (loosening or separation of a fingernail or toenail from its nail bed)
- dandruff (small pieces of dead skin in your hair)
- red, swollen and sore skin sometimes with small blisters
- abnormal hair growth

- patchy loss of skin colour, which usually first appears on the hands and face
- pain and heaviness in the arms and legs, involuntary contractions of a muscle, pain in your bones
- itching, irritation or sore in or around the vagina, vaginal discharge
- swelling of all or part of the breast(s), breast lumps.

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 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 DIENOGEST ADCO.

5. How to store DIENOGEST ADCO

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

Store at or below 30 °C.

Store in the outer carton box packaging to protect from light.

Do not use after the expiry date stated on the label / carton / bottle.

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 ADCO contains

The active substance is dienogest.

The other ingredients are: crospovidone, type A, lactose monohydrate, magnesium stearate, microcrystalline cellulose, povidone K30, pregelatinised maize starch and

silica colloidal anhydrous.

What DIENOGEST ADCO looks like and contents of the pack

DIENOGEST ADCO is white to slightly yellowish round tablet marked with “D2” on one side and without marking on the other side, with a diameter of approximately 7 mm.

DIENOGEST ADCO are packaged in blister packs of green polyvinyl chloride (PVC) coated with polyvinylidene chloride (PVDC) and push-through heat-sealed aluminium (Alu) foil, packed into carton boxes.

Pack sizes are 28, 84, and 168.

Not all pack sizes may be marketed.

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