PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S3**

Endoact 2 mg tablets

Dienogest

Contains sugar: Each tablet contains 60,93 mg lactose monohydrate.

Read all of this leaflet carefully before you start taking ENDOACT

- 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.
- ENDOACT 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 ENDOACT is and what it is used for

ENDOACT is a hormone preparation for the long-term treatment of endometriosis (painful symptoms due to displaced tissue of the lining of the womb). ENDOACT contains a hormone, the progestogen dienogest. ENDOACT tablets cause the shrinking of the endometrial tissue and reduces associated complaints such as

pelvic pain and painful monthly bleedings. ENDOACT is for use in adolescents after menarche (first menstrual bleeding) from 12 years of age onward, and adults.

2. What you need to know before you take ENDOACT

Do not take ENDOACT:

- If you are hypersensitive (allergic) to dienogest or any of the other ingredients of ENDOACT (listed in section 6);
- if you are suffering from a blood clot (thromboembolic disorder) in your veins. Thrombosis is the formation of blood clots which block blood vessels. 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 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;
- 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 instance, 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 using ENDOACT, stop taking it at once or consult your doctor.

Warnings and precautions

Take special care with ENDOACT 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;
- have a close relative who has had breast cancer;
- have ever suffered from depression;
- have high blood pressure or develop high blood pressure while taking ENDOACT
- develop a liver disease while taking ENDOACT. 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;
- have diabetes or had diabetes temporarily during previous pregnancy;
- 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;
- suffer from pain in your lower abdomen while taking ENDOACT.

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

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

While taking ENDOACT your chance of becoming pregnant is reduced because ENDOACT may affect ovulation. See section “Pregnancy, breastfeeding and fertility”.

If you become pregnant while taking ENDOACT 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 ENDOACT, if you had an extrauterine pregnancy in the past or have an impaired function of the fallopian tubes.

ENDOACT 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 ENDOACT. 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 ENDOACT.

ENDOACT and changes in bleeding pattern

Most women treated with ENDOACT experience changes in their menstrual bleeding pattern (see section 4, “Possible side effects”).

ENDOACT 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 ENDOACT. 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 immobilised for a long time. It is important to tell your doctor in advance that you are using ENDOACT as the treatment may have to be stopped. Your doctor will tell you when to start ENDOACT again. This is usually about two weeks after you are back on your feet.

ENDOACT and cancer

There is a risk of having breast cancer diagnosed while taking ENDOACT.

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.

ENDOACT and osteoporosis

Changes in bone mineral density (BMD)

The use of ENDOACT 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 ENDOACT for you as an individual patient, taking into account possible risk factors for bone loss (osteoporosis).

If you use ENDOACT, 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 ENDOACT because ENDOACT has a moderate suppressing effect on the production of oestrogen (another type of female hormone) by your body.

Children and adolescents

ENDOACT is not for use in girls under 12 years of age, before menarche (first menstrual bleeding).

The use of ENDOACT 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 ENDOACT for you as an individual patient, taking into account possible risk factors for bone loss (osteoporosis).

Other medicines and ENDOACT

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

The following may reduce the effects of ENDOACT:

- 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

The following may increase the levels of ENDOACT 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 ENDOACT, because ENDOACT can affect the results of some tests.

ENDOACT with food and drink

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

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 this medicine.

While taking ENDOACT your chance of becoming pregnant is reduced because ENDOACT may affect ovulation. ENDOACT must not be used by women who are breastfeeding, or who are pregnant, or who think they may be pregnant.

Driving and using machines

You should be aware of how you react to ENDOACT before you drive or operate machinery. If you feel dizzy or drowsy after taking ENDOACT, do not drive or operate machinery until these effects wear off.

ENDOACT contains lactose monohydrate

Lactose is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking ENDOACT.

3. How to take ENDOACT

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

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

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

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 ENDOACT 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 for 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 ENDOACT will last.

If you have the impression that the effect of ENDOACT is too strong or too weak, tell your doctor or pharmacist.

If you take more ENDOACT 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 ENDOACT

ENDOACT will be less effective if you miss a tablet.

If you miss one or more tablets, take one tablet only as soon as you remember, and then continue the next day taking the tablet at your usual time.

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

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

If you have missed several doses, consult your doctor.

If you stop taking ENDOACT

If you stop taking ENDOACT, your original endometriosis symptoms may return.

Do not stop taking/using ENDOACT unless your doctor tells you to.

If you have any further questions on how to take this medicine ask your doctor or pharmacist.

4. Possible side effects

ENDOACT can have side effects.

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

If any of the following happens, stop taking ENDOACT 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;
- skin rash, lesions, itchiness of the skin, blistering or peeling of the skin or any other type of skin irritation; or
- chest tightness, difficulty breathing, feeling dizzy or fainting due to low blood pressure.

These are all very serious side effects. If you have them, you may have had a serious reaction to ENDOACT. 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 a blood clot:

- 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.

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;
- unspecific circulatory problems or uncommon palpitations;
- 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 (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 healthcare professional. This includes any possible side effects not listed in this leaflet. You can report side effects to Actor Pharma (Pty) Ltd via email: pharmacovigilance@actorpharma.co.za or telephonically on 011 312 3812. 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 ENDOACT.

5. How to store ENDOACT

Store at or below 25 °C in a cool, dry place.

Store in the original packaging to protect from light and moisture.

Store all medicines out of reach of children.

Do not refrigerate or freeze.

Do not use after the expiry date stated on the carton and blister strip.

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 ENDOACT contains

The active substance is dienogest.

Each tablet contains 2 mg dienogest.

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

What ENDOACT looks like and contents of the pack

Tablets.

Round plain white tablets.

The tablets are packed into blister packs consisting of clear to a slightly opaque film made of polyvinylidene chloride (PVDC) coated polyvinyl chloride (PVC), sealed onto push through aluminium foil (dull side lacquered, and bright side heat sealable lacquered).

Pack sizes: 2 X 14, 6 X 14, and 12 X 14 tablets.

Not all pack sizes may be marketed.

The blisters are contained in an outer cardboard carton.

Holder of certificate of registration

Actor Pharma (Pty) Ltd[1]

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Access to the corresponding professional information

The corresponding Professional Information is available electronically on www.actorpharma.co.za.

Alternatively, to obtain this Professional Information please contact Actor Pharma (Pty) Ltd on 011 312 3812 or email info@actorpharma.co.za.

[1] Company Registration Number.: 2008/008787/07