PATIENT INFORMATION LEAFLET FOR MEDINOR™ 1,5 mg TABLET

SCHEDULING STATUS **S2**

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

MEDINOR™ 1,5 mg tablet

Read all of this leaflet carefully because it contains important information for you.

- MEDINOR is available without a doctor's prescription, for you to treat a condition. Nevertheless, you still need to use MEDINOR carefully to get the best results from it.
- Keep this leaflet. You may need to read it again.
- Do not share MEDINOR with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if you think you still became pregnant after using MEDINOR.

1. WHAT MEDINOR CONTAINS

Active ingredient: Each tablet contains 1,5 mg levonorgestrel.

Inactive ingredients: Colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch, povidone.

Contains sugar: lactose monohydrate.

2. WHAT MEDINOR IS USED FOR

MEDINOR is an oral emergency contraceptive.

MEDINOR is recommended in the following situations:

The prevention of pregnancy within 72 hours of unprotected sexual intercourse, particularly:

- If you have had sexual intercourse where either you or your partner did not use a contraceptive method
- If your partner's condom has broken, slipped or been improperly removed, or if he has forgotten to use one
- If you fear that your intrauterine device has been expelled
- If your vaginal diaphragm or contraceptive cap has moved or if you have removed it too early
- If you are afraid that the method of coitus interruptus (sexual intercourse in which the penis is withdrawn before ejaculation) has failed or if you have had sexual intercourse during the period when you are supposed to be fertile when using the rhythm method
- In the event of rape

MEDINOR is intended for emergencies only and is completely unsuitable for regular contraception. Its reliability is not as high as that of the familiar "pill", which is taken for at least 21 days of the menstrual cycle.

3. BEFORE YOU TAKE MEDINOR

Do not take MEDINOR:

- If you are hypersensitive (allergic) to levonorgestrel or any of the inactive ingredients of MEDINOR (see WHAT MEDINOR CONTAINS).
- If there is a possibility that pregnancy already exists, e.g. if unprotected sexual intercourse has already taken place in the same cycle or if the last menstrual period failed to occur.
- In the case of abnormal vaginal bleeding.
- In the case of severe liver problems.
- If you have a history of a blood circulation problem because of narrowed arteries.
- If you have had a cancer that was influenced by hormones.
- If you have had trophoblastic disease (a condition in which tumours grow inside a woman's womb).
- If you have had an ectopic pregnancy (a pregnancy in which the fetus develops outside the womb, typically in the fallopian tube).
- If you have porphyria (a rare hereditary disease in which there is abnormal metabolism of the blood protein haemoglobin).
- If you have already taken MEDINOR within the same monthly cycle.

Take special care with MEDINOR:

Emergency contraception must be used exceptionally; since:

- It does not prevent a pregnancy in every instance.
- The associated hormonal overdosing is not advisable in the case of regular intake.
- It cannot replace a regular contraception.
- It cannot interrupt a pregnancy.

Take special care with MEDINOR if you have any of the following diseases:

- Malabsorption syndrome (an alteration in the ability of the intestines to absorb nutrients adequately)
- Liver problems
- Ovarian cyst (a fluid filled sac in the ovary)
- Diabetes mellitus (a condition in which the pancreas no longer produces enough insulin or cells stop responding to the insulin produced)
- High blood pressure

- Migraine
- Thromboembolic disorder (a condition in which a blood clot formed inside one blood vessel is carried by the blood from the site of origin to block another vessel)
- Epilepsy
- Asthma
- Heart and kidney problems
- Depression

Pregnancy and breastfeeding:
If you are pregnant, planning to become pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking MEDINOR.
MEDINOR is secreted into breast milk and breastfeeding should not occur within 6 hours of taking MEDINOR.

Driving and using machinery:
MEDINOR may make you feel drowsy or dizzy. Do not drive a vehicle or operate any machinery or tools requiring your attention, until you know how MEDINOR will affect you.

Important information about some of the ingredients of MEDINOR:
MEDINOR contains a sugar called lactose. If you have been told by your doctor that you cannot tolerate or digest some sugars, consult your doctor before taking MEDINOR.

Taking other medicines with MEDINOR:
Always tell your healthcare professional if you are taking any other medicine (this includes complementary or traditional medicine).
The efficacy of MEDINOR may be decreased if you are taking the following medicines:

- Anticonvulsants that contain phenobarbitone, phenytoin, primidone or carbamazepine
- Rifabutin, rifampicin (used to treat bacterial infections)
- Griseofulvin (used to treat fungal infections)
- Ritonavir [used in the treatment of human immunodeficiency virus (HIV)]
- St John's wort (*Hypericum perforatum)* (used in the treatment of anxiety or mild to moderate depression)

4. HOW TO TAKE MEDINOR
Do not share your medicines with any other person.

Always take MEDINOR exactly as your pharmacist has instructed you. You should check with your pharmacist if you are unsure.

- Take one MEDINOR 1,5 mg tablet as soon as possible, preferably within 12 hours and not later than 72 hours (3 days) after unprotected sexual intercourse.
- MEDINOR can be taken at any time during the menstrual cycle.
- The earlier MEDINOR is used, the more effective it is. Even extremely high doses of hormone can no longer prevent pregnancy once a fertilised ovum has become implanted in the uterus.
- All further unprotected sexual intercourse must be avoided until the next menstrual period; until then only mechanical and/or chemical methods (condoms, foam and pessary) of contraception may be used.

If you take more MEDINOR than you should:
In the event of an overdosage or suspected overdosage consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Effects when treatment with MEDINOR is stopped:
The menstrual period may occur earlier or later than usual. At all events, you should visit your doctor 3 weeks after taking MEDINOR regardless of whether bleeding has occurred or not.

5. POSSIBLE SIDE EFFECTS
MEDINOR can have side effects.
Not all side effects reported for MEDINOR are included in this leaflet.
Should your general health worsen or if you experience any untoward effects while taking MEDINOR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking MEDINOR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of your 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 MEDINOR. 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:

- Yellowing of the skin and eyes, also called jaundice
- Blood clot formation

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

Tell your doctor as soon as possible if you notice any of the following:

Frequent:

- Premenstrual syndrome-like symptoms
- Altered menstrual cycle or irregular menstrual bleeding, breakthrough bleeding
- Weight changes
- Nervousness, mood changes
- Drowsiness, dizziness, headache
- Abdominal pain or cramping, diarrhoea, nausea (feeling sick), vomiting (being sick)
- Breast tenderness
- Fatigue
- Swelling of hands, ankles or feet (oedema)
- High sugar (glucose) levels in the blood (you may experience symptoms such as increased thirst, frequent urination, fatigue, nausea (feeling sick) and vomiting (being sick), shortness of breath, stomach pain, fruity breath odour or a very dry mouth)

Less frequent:

- Appetite changes
- Fluid retention
- Depression
- Unable to sleep
- Excessive hairiness
- Alteration in liver function test
- Acne, allergic skin reaction
- Darkening of parts of the skin
- Hair loss (temporary)
- Unusual secretion of breast milk
- Changes in sex drive
- Hypotension (low blood pressure)
- Adrenal glands (a small gland above the kidney) not working properly
- Hot flushes

- Cushing's syndrome (condition of the adrenal glands causing weight gain, rounded face and high blood pressure)

Frequency unknown:

- Fever, itchy rash (urticaria)
- Loss of bone density, brittle bones that can fracture easily
- Alterations in cholesterol levels
- Gastrointestinal disturbances

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

6. STORING AND DISPOSING OF MEDINOR

Store in a cool place at or below 25 °C. Protect from moisture and light.
Keep the blister strip in the outer carton until required for use.
STORE ALL MEDICINES OUT OF REACH OF CHILDREN.
Do not take the tablets after the expiry date printed on the carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF MEDINOR

1 tablet in PVC complex (PVC/PE/PVDC orange) and aluminium foil blister strip. The blister strip is enclosed in an outer cardboard carton.

8. IDENTIFICATION OF MEDINOR

White, round, biconvex tablet with the code "NL 1.5" engraved on one side.

9. REGISTRATION NUMBER

44/21.8.2/0810

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Actor Pharma (Pty) Ltd1
Unit 7, Royal Palm Business Estate
646 Washington Street
Halfway House, Midrand, 1685
Gauteng, South Africa

11. DATE OF PUBLICATION

26 November 2015

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[1] Company Registration number: 2008/008787/07

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