

PATIENT INFORMATION LEAFLET FOR NORLEVO® 0,75 mg TABLETS

Read all of this leaflet carefully before you take this medicine.

This medicine is available without a doctor's prescription, for you to treat a condition.

Nevertheless, you still need to use **NORLEVO** carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if you think you still became pregnant after using this medicine.

SCHEDULING STATUS:

S2

THE PROPRIETARY NAME OF THE MEDICINE:

NORLEVO® Tablet

0,75 mg Levonorgestrel.

WHAT THIS MEDICINE CONTAINS:

The active substance is 0,75 mg Levonorgestrel.

The tablets also contain the following other ingredients: Lactose monohydrate, maize starch, povidone, anhydrous colloidal silica, and magnesium stearate.

WHAT THIS MEDICINE IS USED FOR:

NORLEVO is an oral emergency contraceptive.

NORLEVO 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 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

NORLEVO 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.

BEFORE TAKING THIS MEDICINE:

Do not use NORLEVO:

- If you have an allergy to any of the ingredients.
- 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 hepatic impairment.
- If you have a history of arterial disease.
- If you have had an ectopic pregnancy.

Take special care with NORLEVO:

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.

The efficacy of **NORLEVO** may be decreased if you are taking other medicines like anticonvulsants that contain phenobarbitones, phenytoin, primidene or carbamazepine.

Other medicines that contain rifabutin, rifampicin, griseofulvin, ritonavir, Hypericum perforatum (St John's wort) can also decrease the efficacy of **NORLEVO**.

Pregnancy and Lactation:

NORLEVO is secreted into breast milk and breastfeeding should not occur within 6 hours of taking **NORLEVO**.

If you are pregnant, this medicine must not be used. If you are breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice.

Taking other medicines with NORLEVO:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **NORLEVO** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

HOW TO TAKE THIS MEDICINE:

- The treatment necessitates the intake of **two tablets** as a **single dose** as soon as possible, **preferably within 12 hours and not later than 72 hours (3 days) after unprotected sexual intercourse.**
- **NORLEVO** can be taken at any time during the menstrual cycle.

The earlier **NORLEVO** 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; till then only mechanical and/or chemical methods (condoms, foam, pessary) of contraception may be used.

POSSIBLE SIDE EFFECTS:

The side effects of **NORLEVO** may include:

- Nausea and vomiting; changes in appetite or weight; fluid retention; dizziness, fatigue, headache; allergic skin reactions; a feeling of breast tenderness
- Altered menstrual cycles or irregular menstrual bleeding

The menstrual period may occur earlier or later than usual. At all events, you should visit your doctor 3 weeks after taking **NORLEVO** regardless of whether bleeding has occurred or not

STORING AND DISPOSING OF NORLEVO:

Do not share medicines prescribed for you with others.

Keep all medicines out of reach and sight of children.

Do not take the tablets if they are past the expiry date on the box.

Do not store the tablets above 25 °C and protect it from moisture and light.

IDENTIFICATION OF NORLEVO:

The tablets are white, round and biconvex t with “NL” engraved on both faces.

PRESENTATION OF NORLEVO:

2 Tablets are packed in an orange plastic foil sealed on aluminium foil blister strips.

1 Blister strip with two tablets is packed in a printed cardboard box.

REGISTRATION NUMBER:

33/21.8.2/0471

NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER:

Actor Pharma (Pty) Ltd¹

Royal Palm Business Estate

Unit 7, 646 Washington Street

Halfway House, Midrand, 1685

DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

7 April 2006

® Norlevo is a registered trademark of Actor Pharma

¹ Company Reg No: 2008/008787/07

<p>Namibia: Registration number: 11/21.8.2/0207 Scheduling status: NS1</p>
