PATIENT INFORMATION LEAFLET FOR NORLEVO

SCHEDULING STATUS: **S2**

THE PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

NORLEVO Tablet

0,75 mg Levonorgestrel.

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

NORLEVO 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.
- Do not share NORLEVO 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 NORLEVO.

WHAT NORLEVO 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 NORLEVO IS USED FOR:

NORLEVO is an oral emergency contraceptive.

NORLEVO is recommended in the following situations:

The prevention of pregnancy as soon as possible but within 72 hours of unprotected sexual intercourse, e.g.:

- 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 works by stopping your ovaries from releasing an egg. It cannot stop a fertilised egg from attaching to the womb.

NORLEVO is intended for emergencies only and is completely unsuitable for regular contraception.

BEFORE TAKING NORLEVO:

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 liver function 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 only in the specific circumstances of “What NORLEVO is used for” as above; 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 abort a pregnancy.

The use of NORLEVO is not recommended in the following cases:

- if you have had an infection in your fallopian tubes (salpingitis),
- if you have a severe digestive disease which impairs absorption of food and medications,
- or if you have a severe disease of the small bowel, such as Crohn’s disease

If you have had another act of unprotected intercourse more than 72 hours ago, conception may have occurred. Treatment with NORLEVO following the second act of intercourse may therefore be ineffective in preventing pregnancy.

After the use of NORLEVO, your period is usually normal and will start on the expected day; however sometimes, this will be a few days later or earlier. If your period is more than five days late or is unusually light or unusually heavy, or if you think that you might be pregnant for any other reason, you should check whether you are pregnant by performing a pregnancy test. If you do become pregnant even after taking NORLEVO, it is important that you see your doctor.

Studies suggest that NORLEVO is less effective in women weighing 75 kg or more and is not effective in women weighing more than 80 kg. Ask your doctor or pharmacist for advice on alternative methods of emergency contraception if you weigh 75 kg or more.

Cases of blood clotting (thromboembolic events) have been reported after taking NORLEVO. Tell your doctor if you have an existing blood clotting disorder or have a family history of blood clotting problems.

PREGNANCY AND BREASTFEEDING:

NORLEVO is secreted into breast milk and breastfeeding should not occur within 8 hours of taking NORLEVO. If you are pregnant, NORLEVO must not be used. If you are breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice.

If you do become pregnant after taking NORLEVO, you should contact your doctor. Your doctor might want to check whether the pregnancy is not ectopic (the baby develops somewhere outside your womb). This is especially important if you develop severe pain in your abdomen after taking NORLEVO or if you ever had an ectopic pregnancy, surgery to your fallopian tubes or pelvic inflammation disease.

DRIVING AND USING MACHINERY:

Dizziness and exhaustion/tiredness have been reported after taking NORLEVO. Do not drive or operate machinery until you know how NORLEVO affects you.

IMPORTANT INFORMATION ABOUT SOME OF THE INGREDIENTS OF NORLEVO:

NORLEVO contains lactose (milk sugar). If you know or have been told by your doctor that you cannot tolerate (have intolerance) lactose, you should not take NORLEVO.

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.

The efficacy of NORLEVO may be decreased if you are taking other medicines like anticonvulsants (medicines for seizures) that contain phenobarbitone, phenytoin, primidone or carbamazepine.

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

NORLEVO should not be used with other medicines containing ulipristal acetate (medicine for uterine fibroids and/or emergency contraception)

HOW TO TAKE NORLEVO:

- 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 tablets should be taken with a glass of water and should not be chewed.

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.

If you vomit within three hours of taking the tablets, you should take another two tablets immediately.

If you take more NORLEVO than you should:

If you take more NORLEVO than you should, you may experience nausea, vomiting or vaginal bleeding.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of NORLEVO:

The efficacy of NORLEVO is not guaranteed if one tablet has been omitted. Contact your doctor or pharmacist for advice.

POSSIBLE SIDE EFFECTS:

NORLEVO can have side effects.

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

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

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- Yellowing of the skin and whites of the eyes, also called jaundice

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NORLEVO. You may need urgent medical attention of hospitalisation.

Other 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, hair loss, fever, abdominal pain, diarrhoea, acne, depression, blood clotting.
- 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.

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

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, biconvex tablet engraved with “NL” 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:

NORLEVO - 33/21.8.2/0471

NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER:

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

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