Patient Information Leaflet for NORLEVO 1,5

SCHEDULING STATUS: S2

NORLEVO 1,5 tablet

Levonorgestrel

Contains sugar. Each tablet contains

90,9 mg lactose monohydrate**.**

Read all of this leaflet carefully before you start taking NORLEVO 1,5 tablets.

NORLEVO 1,5 is available without a doctor's prescription, for you to treat a condition.

Nevertheless, you still need to use NORLEVO 1,5 carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NORLEVO 1,5 with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if you think you still became pregnant after using NORLEVO 1,5.

What is in this leaflet

1. What NORLEVO 1,5 is and what it is used for
2. What you need to know before you take NORLEVO 1,5
3. How to take NORLEVO 1,5
4. Possible side effects
5. How to store NORLEVO 1,5
6. Contents of the pack and other information.

1. What NORLEVO 1,5 is and what it is used for

NORLEVO 1,5 is an oral emergency contraceptive.

NORLEVO 1,5 is used in 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- if you are afraid that the method of coitus interruptus (sexual intercourse in which the penis is withdrawn before ejaculation) has failed or if you have had sexual intercourse during the period when you are supposed to be fertile when using the rhythm method;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.

NORLEVO 1,5 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.

2. What you need to know before you take NORLEVO 1,5

Do not take NORLEVO 1,5:

- If you are hypersensitive (allergic) to levonorgestrel or any of the other ingredients of NORLEVO 1,5 (listed in section 6).
- 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 cancer that was influenced by hormones.
- If you have trophoblastic disease (a condition in which tumours grow inside a woman’s womb).
- If you have had, or you are at risk of an ectopic pregnancy (a pregnancy in which the fetus develops outside the womb, typically in the fallopian tube).

- Porphyria (a rare hereditary disease in which there is abnormal metabolism of the blood protein haemoglobin).
- If you had already taken NORLEVO 1,5 within the same monthly cycle.
- If you have depression that is not well controlled with treatment.
- If you have a history of depression with the use of hormonal contraceptives.

Warnings and precautions

Take special care with NORLEVO 1,5:

Emergency contraception must be used only in the specific circumstances listed in section 1; 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 end a pregnancy.

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 1,5, it is important that you see your doctor.

If you have had another act of unprotected intercourse more than 72 hours ago (during the same period cycle), conception may have occurred. Treatment with NORLEVO 1,5 following the second act of intercourse may therefore be ineffective in preventing pregnancy.

There is some evidence that NORLEVO 1,5 may be less effective with increasing body weight or body mass index (BMI). However, NORLEVO 1,5 is recommended for all women regardless of their weight or BMI.

If you still become pregnant after using NORLEVO 1,5, your doctor will closely evaluate you for an

ectopic pregnancy, especially if you have a history of an ectopic pregnancy. A previous ectopic pregnancy and a previous infection of the fallopian tubes increase the risk of a new ectopic pregnancy.

After NORLEVO 1,5 intake, menstrual periods are usually of normal abundance and occur at the expected date. They can sometimes occur earlier or later than expected by a few days. It is recommended to visit your health care provider to initiate or adapt a method of regular contraception.

You must consider long-term methods of contraception if you have had repeated courses of emergency contraception.

The use of emergency contraception does not replace the necessary precautions against sexual transmitted diseases.

Tell your doctor or health care provider if you have any of the following conditions before taking NORLEVO 1,5:

- Endocrine disorders (hormone imbalance). You may experience disturbances in your period after taking NORLEVO 1,5. You must consult your health care provider 3 weeks after taking NORLEVO 1,5.
- Malabsorption syndromes (an alteration in the ability of the intestines to absorb nutrients adequately), such as Crohn’s disease.
- Liver problems.
- Ovarian cyst (a fluid filled sac in the ovary).
- Diabetes mellitus (also known as high blood sugar, is a condition in which the pancreas no longer produces enough insulin or cells stop responding to the insulin produced).
- High blood pressure.
- Migraine (severe headache).
- Thromboembolic disorder or if you or a family member has had thrombophilia (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 (fits/seizures).
- Asthma.
- Heart and kidney problems.
- A condition which is being treated with medicines containing ulipristal acetate (used to treat uterine fibroids and/or emergency contraception. see Other medicines and NORLEVO 1,5).
  Severe depression is associated with a higher risk of suicidal thoughts/behaviour (e.g. talking about suicide, withdrawing from social contact, having mood swings, being preoccupied with death or violence, feeling hopeless about a situation, increasing use of alcohol/drugs, doing self-destructive things, personality changes) and suicide. If you experience mood changes and depression, contact your doctor for advice.

Children and adolescents

NORLEVO 1,5 is not for use in children and adolescents below 16 years of age.

Other medicines and NORLEVO 1,5

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

The efficacy of NORLEVO 1,5 may be decreased if you are taking the following medicines:

- Anticonvulsants that contain phenobarbitone, phenytoin, primidone or carbamazepine (used to treat seizures/fits).
- Rifabutin, rifampicin (used to treat tuberculosis (TB)).
- Griseofulvin (used to treat fungal infections).
- Ritonavir, efavirenz (used in the treatment of human immunodeficiency virus (HIV)).
- St John's wort (*Hypericum perforatum*) (herbal medicine used in the treatment of anxiety or mild to moderate depression).
- Ciclosporin (used to treat organ rejection after a transplant).
- Medicines containing ulipristal acetate (used in the treatment of uterine fibroids and/or

emergency contraception).

- Antidiabetics (medicines used to lower your blood sugar levels).

Some medicines may prevent NORLEVO 1,5 from working effectively. These include medicines used to treat epilepsy (such as phenobarbital, phenytoin, primidone, carbamazepine), tuberculosis (rifampicin, rifabutin), HIV infection (efavirenz, ritonavir), fungal infections (griseofulvin), and certain herbal remedies (St John's wort). If you have used any of the medicines above during the last four weeks, NORLEVO 1,5 may be less suitable for you. Your doctor may prescribe another type of (non-hormonal) emergency contraceptive, i.e. a copper intrauterine device (Cu-IUD). If you are unable or unwilling to use a copper IUD, then your doctor might advise you to take a double dose (2 tablets) of NORLEVO 1,5 (see section 3).

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 health care provider for advice before taking NORLEVO 1,5.

Do not take NORLEVO 1,5 if you are pregnant.

There is no evidence that NORLEVO 1,5 will harm a baby that develops in your uterus (womb) if you use NORLEVO 1,5 as described.

NORLEVO 1,5 is secreted into breast milk and breastfeeding should not occur within 8 hours of taking NORLEVO 1,5.

A rapid return to fertility is likely following treatment with NORLEVO 1,5 for emergency contraception. Therefore, regular contraception should be continued or initiated as soon as possible following the use of NORLEVO 1,5 to ensure ongoing prevention of pregnancy.

Driving and using machines

NORLEVO 1,5 may make you feel drowsy or dizzy which may affect your ability to drive a vehicle or operate machinery. Do not drive a vehicle or operate any machinery or tools requiring your attention, until you know how NORLEVO 1,5 will affect you.

NORLEVO 1,5 contains lactose

NORLEVO 1,5 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 NORLEVO 1,5.

3. How to take NORLEVO 1,5

Do not share your medicines with any other person.

Always take NORLEVO 1,5 exactly as described in this leaflet or as your doctor, pharmacist or nurse have instructed you. You should check with your doctor, pharmacist or nurse if you are unsure.

- Take one NORLEVO 1,5 tablet as soon as possible, preferably within 12 hours and not later than 72 hours (3 days) after unprotected sexual intercourse.
- NORLEVO 1,5 can be taken at any time during the menstrual cycle unless your bleeding (period) is overdue.
- The earlier NORLEVO 1,5 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 are already using a regular method of contraception, such as the contraceptive pill, you can continue to take this at your regular scheduled times.
- If you vomit within three to four hours of taking the tablet, you should take another tablet immediately.
- If you have used any medicines listed in section 2 (Other medicines and NORLEVO 1,5) in the last four weeks and need emergency contraception, please consult your doctor as some of

these medicines may require that you use a non-hormonal emergency contraception, i.e. a copper intrauterine device (IUD) instead. If you are unable or unwilling to use a copper IUD, then your doctor might advise you to take a double dose (2 tablets) of NORLEVO 1,5.

- You should visit your doctor 3 weeks after taking NORLEVO 1,5 regardless of whether bleeding has occurred or not.

If you take more NORLEVO 1,5 than you should

If you take more NORLEVO 1,5 than you should, you may experience nausea, vomiting or vaginal bleeding.

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.

If you forget to take NORLEVO 1,5

NORLEVO 1,5 should be taken as soon as possible, preferably within 12 hours and not later than 72 hours (3 days) after unprotected sex. If you forget to take it, or delay taking it, it may not work as effectively. Take the tablet as soon as you remember. Do not take more than one tablet at the same time to make up for a missed dose. Always use a barrier method (such as a condom) until your next menstrual period to reduce the risk of pregnancy.

4. Possible side effects

NORLEVO 1,5 can have side effects. Not all side effects reported for NORLEVO 1,5 are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking NORLEVO 1,5, please consult your health care provider for advice.

If any of the following happens, stop taking NORLEVO 1,5 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 NORLEVO 1,5. 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:

- Yellowing of the skin and eyes, also called jaundice.
- Blood clot formation.
- Suicidal thoughts/behaviour and suicide.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Premenstrual syndrome-like symptoms.
- Uterine (period) pain, very painful periods, bleeding not related to periods.
- Altered menstrual cycle, the menstrual period may occur earlier or later than usual or irregular menstrual bleeding, breakthrough bleeding.
- Weight changes.
- Nervousness, mood changes.
- Drowsiness, dizziness, headache.
- Abdominal (stomach) pain or cramping, diarrhoea (frequent, loose, watery stools), nausea (feeling sick), vomiting (being sick).
- Breast tenderness.
- Fatigue (tiredness).
- Swelling of hands, ankles or feet due to excessive fluid build-up/water retention (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 side effects:

- Depression.
- Unable to sleep.
- Excessive/unusual hair growth.
- Alteration in liver function test.
- Acne, allergic skin reactions.
- 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).

Side effects which may occur but the frequency is unknown:

- Fever, hives (urticaria).
- Loss of bone density, brittle bones that can fracture easily.
- Alterations in cholesterol levels.
- Appetite changes.
- Gastrointestinal disturbances.

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of NORLEVO 1,5 is important. If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA

via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of NORLEVO 1,5.

5. How to store NORLEVO 1,5

- Store all medicines out of reach of children.
- Store at or below 25 °C.
- Protect from light and moisture.
- Keep the blister strip in the outer carton until required for use.
- 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).

6. Contents of the pack and other information

What NORLEVO 1,5 contains

The active substance is 1,5 mg levonorgestrel.

The other ingredients are colloidal anhydrous silica, lactose monohydrate, magnesium stearate, maize starch and povidone.

What NORLEVO 1,5 looks like and contents of the pack

The tablets are white, round and biconvex with the code ‘NL 1.5’ engraved on oneside.

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

Holder of certificate of registration

CIPLA MEDPRO (PTY) LTD.

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