Scheduling status: S2

Proprietary name and dosage form:

Norlevo® Tablet

Composition:
Each NORLEVO Tablet contains 0,75 mg Levonorgestrel.

Pharmacological classification:
A 21.8.2 Progesterones with or without oestrogens

Pharmacological action:
Levonorgestrel acts as a contraceptive by inhibiting ovulation and preventing the nidation of a fertilised ovum in the uterine mucosa.

Pharmacokinetics:
Oral bioavailability of levonorgestrel is approximately 100 %. In the plasma it is strongly bound to SHBG. Levonorgestrel is eliminated metabolically via the kidney (60 – 80 %) and liver (40 – 50 %).
After oral administration of 1,5 mg levonorgestrel the plasma terminal half-life is estimated to be 43 hours. The maximal plasma concentration (approximately 40 nmol/l) is reached within 3 hours. Levonorgestrel is hydroxylated in the liver and the metabolites are excreted as glucoronide conjugates.

Indications:
NORLEVO is indicated for the prevention of pregnancy within 72 hours of unprotected sexual intercourse or the recognisable failure of mechanical methods.
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.

Contra-indications:
Pregnancy.
NORLEVO should not be used 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.
Hypersensitivity to any of the ingredients.
NORLEVO should not be given to patients with undiagnosed vaginal bleeding, nor to those with a history of or current high risk of arterial disease.
Severe hepatic impairment.
The repeated use of NORLEVO within a monthly cycle is to be avoided, since it constitutes undesirable hormonal stress and may result in severe cycle disturbances.

Warnings:
Patients who become pregnant despite emergency contraception should be carefully evaluated for ectopic pregnancy.
Therefore, NORLEVO is not recommended for patients who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy).

The effect of NORLEVO on the conceptus in the event of a failure to prevent conception is not definitely known. Therefore, a pregnancy test must be performed if there is any doubt.

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.

Interactions:
Interactions with other medicines:
The metabolism of NORLEVO is enhanced by the concomitant use of liver enzyme inducers: anticonvulsants (phenobarbitones, phenytoin, primidene, carbamazepine); rifabutin, rifampicin, griseofulvin, ritonavir, Hypericum perforatum (St John's wort). The efficacy of NORLEVO may be decreased in cases of concomitant intake of the above mentioned medicines.

Pregnancy and lactation:
NORLEVO is not indicated in pregnancy.
NORLEVO is secreted into breast milk and breastfeeding should not occur within 6 hours of administration of NORLEVO (See contra-indications).

Dosage and directions for use:
Take two tablets in a single administration as soon as possible, preferably within 12 hours, but not later than 72 hours after unprotected sexual intercourse.
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 uterine mucosa.
All further unprotected sexual intercourse must be avoided until the next menstrual period; until then, only mechanical and/or chemical methods (condom, foam, pessary) of contraception may be used.

Side effects and special precautions:
The following table gives the frequency of undesirable effects reported in clinical trials.

Body system:	**Frequency of adverse reaction:** Very common (> 1/10)	**Frequency of adverse reaction:** Common (> 1/100)
Endocrine system	Bleeding not related to menses	Delay of menses more than 7 days Irregular bleeding and Spotting
Nervous system:		Dizziness, Headache
Gastro-intestinal system:		Nausea, Diarrhoea, Low abdominal pain, Vomiting
Reproductive system and breast:		Breast tenderness
General:		Fatigue

Side-effects:
The following side-effects have been reported and the frequencies are unknown.

Gastro-intestinal disorders:
Gastro-intestinal disturbances.

Endocrine disorders:
Premenstrual syndrome-like symptoms and altered menstrual cycles or irregular menstrual bleeding.
Certain progesterones may have an adverse effect on serum lipids.

Metabolism and nutrition disorders:
Changes in appetite or weight and fluid retention as well as oedema.

Skin and subcutaneous tissue disorders:
Acne, melasma or chloasma, allergic skin reactions, urticaria, hair loss or hirsutism and fever.

Psychiatric disorders:
Mental depression.

Reproductive system and breast disorders:
Breast changes, including discomfort or less frequently gynaecomastia and changes in libido.

Nervous system disorders:
Fatigue, drowsiness or insomnia.

Vascular disorders:
Headache.

Immune system disorders:
Anaphylaxis or anaphylactoid reactions may occur less frequently.

Hepato-billiary disorders:
Alterations in liver function tests have been reported.
Jaundice has been reported less frequently during prolonged levonorgestrel administration.

Special precautions:
Pregnancy, puerperium and perinatal conditions:
NORLEVO is not recommended for patients who are at risk of an ectopic pregnancy.
NORLEVO should not be used diagnostically for pregnancy testing and should not be given in missed or incomplete abortion.
The use of emergency contraception does not replace the necessary precautions against sexually transmitted diseases.

Endocrine disorders:
The next menstrual period may occur earlier or later than usual. A health professional should be consulted 3 weeks after taking NORLEVO regardless of whether bleeding has occurred or not.

Psychiatric disorders:
NORLEVO should be used with caution in patients with a history of mental depression.

Known symptoms of overdosage and particulars of its treatment:
(see "Side-effects and special precautions").
Treatment is symptomatic and supportive.

Identification:
White, round, biconvex tablet with "NL" engraved on both faces.

Presentation:
2 tablets in orange PVC/PE/PVDC plastic foil sealed on aluminium foil blister strips.
1 blister strip packed in a printed cardboard box.

Storage instructions:
Store in a cool place below 25 °C.
Protect from moisture and light.
KEEP OUT OF THE REACH OF CHILDREN.

Registration number:
33/21.8.2/0471

Name and business address of the holder of the certificate of registration:
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Date of publication of this package insert:
07 April 2006

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