Size : 293 x 113

Front

Levonorgestrel Tablets BP 1.5 mg

ZEE-1

Levonorgestrel Tablets BP 0.75 mg

ZEE-2

Prescription Only Medicines

Zee-1
Each uncoated tablet contains
Levonorgestrel BP 1.5 mg
Excipients Q.S.

Zee-2
Each uncoated tablet contains
Levonorgestrel BP 0.75 mg
Excipients Q.S.

Pharmacological properties

Pharmacodynamic properties

Pharmacotherapeutic group: Emergency Contraceptives

Mechanism of Action

The primary mechanism of action is blockade and/or delay of ovulation via suppression of the luteinizing hormone (LH) peak. Levonorgestrel interferes with the ovulatory process only if it is administered before the onset of the LH surge. Levonorgestrel has no emergency contraceptive effect when administered later in the cycle.
In clinical trials, the proportion of pregnancies avoided after the use of levonorgestrel varied from 52% to 85% of expected pregnancies. Efficacy appears to decline with time after inter course.
In clinical trials, contraceptive efficacy was reduced in women weighing 75 kg or more and levonorgestrel was not effective in women who weighed more than 80 kg.
At the used regimen, levonorgestrel is not expected to induce significant modifications of blood clotting factors, and lipid and carbohydrate metabolism.

Pharmacokinetic properties

Bioavailability of oral levonorgestrel is approximately 100 percent. In the plasma, it is strongly bound to SHBG. Levonorgestrel is eliminated via kidney (60-80%) and liver (40-50%).
After oral administration of 1.5 mg levonorgestrel, the plasma terminal half-life of the product is estimated to 43 hours. The maximal plasma concentration of levonorgestrel (approximately 40 nmol/l) is reached within 3 hours.
Levonorgestrel is hydroxylated in the liver and the metabolites are excreted as glucuronide conjugates.

Indications : Emergency contraception within 72 hours after an unprotected sexual intercourse or in case of failure of a contraceptive.

Posology and method of administration

Route of administration: Oral use

Oral use

The treatment necessitates the intake of one tablet. The efficacy of the method is higher the sooner after the unprotected intercourse the treatment is initiated. Therefore, the tablet must be taken as soon as possible, preferably within 12 hours after the unprotected intercourse, and no longer than 72 hours (3 days) after the intercourse.
Levonorgestrel tablets 0.75 mg and 1.5 mg can be taken at any moment during the menstrual cycle.
If vomiting occurs within three hours of taking the tablet, another tablet should be taken immediately. After using an emergency contraception, it is recommended to use a local contraceptive mean (condom, spermicide, and cervical cap) until the next menstrual periods resume. The use of Levonorgestrel tablets 0.75 mg and 1.5 mg does not contraindicate the continuation of regular hormonal contraception.
Special population: Bodyweight 75 kg or more
In clinical trials, contraceptive efficacy was reduced in women weighing 75 kg or more, and levonorgestrel was not effective in women who weighed more than 80 kg.

Contraindications

Hypersensitivity to levonorgestrel or any of the excipients.

Warnings and precautions for use

If the woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, conception may have occurred. Treatment with Levonorgestrel following the second act of intercourse may therefore be ineffective in preventing pregnancy.
In clinical trials, contraceptive efficacy was reduced in women weighing 75 kg or more and levonorgestrel was not effective in women who weighed more than 80 kg.

If pregnancy occurs after treatment with Levonorgestrel, the possibility of an ectopic pregnancy should be considered. The absolute risk of ectopic pregnancy is likely to be low as Levonorgestrel prevents ovulation and fertilisation. Ectopic pregnancy may continue, despite the occurrence of uterine bleeding. Therefore, Levonorgestrel tablet is not recommended for patients who are at risk of ectopic pregnancy (previous history of salpingitis or of ectopic pregnancy).
Levonorgestrel Tablet is not recommended in patients with severe hepatic dysfunction. Severe malabsorption syndromes, such as Crohn's disease, might impair the efficacy of Levonorgestrel Tablet.
Cases of thromboembolic events have been reported after Levonorgestrel Tablet intake. The possibility of occurrence of a thromboembolic event should be considered in women with other pre-existing thromboembolic risk factor(s), especially personal or family history suggesting thrombophilia.
After Levonorgestrel Tablet 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 have a medical visit to initiate or adapt a method of regular contraception. In case no menstrual period occurs in the next pill-free period following the use of Levonorgestrel Tablet after regular hormonal contraception, pregnancy should be ruled out.
Repeated administration within a menstrual cycle is not advisable, because of an undesirable high load of hormones for the patient and the possibility of severe disturbances of the cycle. Women who present for repeated courses of emergency contraception should be advised to consider long-term methods of contraception.
The use of emergency contraception does not replace the necessary precautions against sexually transmitted diseases. Concomitant use of Levonorgestrel Tablet and drugs containing ulipristal acetate is not recommended

Drug interactions

The metabolism of levonorgestrel is enhanced by concomitant use of liver enzyme inducers.
Drugs suspected of having the capacity to reduce the efficacy of levonorgestrel containing medication include barbiturates (including primidone), phenytoin, carbamazepine, herbal medicines containing Hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin, griseofulvin. Women taking such drugs should be referred to their doctor for advice.
Medicines containing levonorgestrel may increase the risk of cyclosporin toxicity due to possible inhibition of cyclosporin metabolism. Women taking cyclosporin containing medication should be referred to their doctor for advice.

Pregnancy and lactation

Pregnancy
Levonorgestrel tablets should not be given to pregnant women. It will not interrupt a pregnancy. In the case of continued pregnancy, limited epidemiological data indicate no adverse effects on the foetus but there are no clinical data on the potential consequences if doses greater than 1.5 mg of levonorgestrel are taken.
Lactation
Levonorgestrel is secreted into breast milk. Potential exposure of an infant to levonorgestrel can be reduced if the breast-feeding woman takes the tablet immediately after feeding and avoids nursing following levonorgestrel administration.

Side effects

The most common adverse events (> 10%) in the clinical trial for women receiving levonorgestrel tablets included menstrual changes (30.9%), nausea (13.7%), abdominal pain (13.3%), fatigue (13.3%), headache (10.3%), dizziness (9.6%), and breast tenderness (8.2%).

Overdosage and its Treatment

Serious effects have not been reported following acute ingestion of large doses of oral contraceptives. Overdose may cause nausea and withdrawal bleeding may occur. There are no specific antidotes and treatment should be symptomatic.

Storage condition

Store below 30 °C. Protect from light and moisture.
Keep out of the reach and sight of children.

Shelf Life: 36 months

Presentation

Zee-1: One Blister of 1 Tablet in a printed carton with a package insert.
Zee-2: One Blister of 2 Tablets in a printed carton with a package insert.

Marketed by:
Sun Enterprises Ltd.
B.P933, Quarter Commercial,
Street KN 70 Kigali, Rwanda.

Manufactured in India by :
CORONA Remedies Pvt. Ltd.
Village. Jatoli, Post Office - Oachghat,
Tehsil Solan, Dist. Solan (H.P)-173 223.INDIA

RW-SE-01

146.5 mm

293 mm

Printing Paper : 45 to 60 GSM

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