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Size : 250x160 mm
Code No. : 20071410
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Front side

100% Pantone 1945 C

160 mm

UNOSURE-72

For the use of a Registered Medical Practitioner or a Hospital or a Laboratory only.

Levonorgestrel Tablets BP

COMPOSITION

Each film coated tablet contains:
Levonorgestrel BP 1.5 mg
Colours: Lake Erythrosine, Lake Indigo
Carmine & Titanium Dioxide BP

PHARMACEUTICAL FORM

Film coated tablet

THERAPEUTIC INDICATION

Emergency contraception within 72 hours of unprotected sexual intercourse or failure of a contraceptive method.

DOSAGE AND ADMINISTRATION

For oral administration:
Posology
One tablet should be taken as soon as possible, preferably within 12 hours, and no later than 72 hours after unprotected intercourse.

If vomiting occurs within three hours of taking the tablet, another tablet should be taken immediately.

Levonorgestrel can be used at any time during the menstrual cycle unless menstrual bleeding is overdue.

After using emergency contraception it is recommended to use a barrier method until the next menstrual period starts. The use of Levonorgestrel does not contraindicate the continuation of regular hormonal contraception.

Paediatric population
Levonorgestrel is not recommended in children. Very limited data are available in women under 16 years of age.

CONTRAINDICATIONS

Hypersensitivity to the active substance.

SPECIAL WARNINGS AND PRECAUTIONS

Emergency contraception is an occasional method. It should in no instance replace a regular contraceptive method.

Emergency contraception does not prevent a pregnancy in every instance. If there is uncertainty about the timing of the unprotected intercourse or 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. If menstrual periods are delayed by more than 5 days or abnormal bleeding occurs at the expected date of menstrual periods or pregnancy is suspected for any other reason, pregnancy should be excluded.

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 is not recommended for patients who are at risk of ectopic pregnancy.

Levonorgestrel is not recommended in patients with severe hepatic dysfunction.

Severe malabsorption syndromes, such as Crohn's disease, might impair the efficacy of Levonorgestrel.

After Levonorgestrel intake, menstrual periods are usually normal and occur at the expected date. They can sometimes occur earlier or later than expected by a few days. Women should be advised to make a medical appointment to initiate or adopt a method of regular contraception. If no withdrawal bleed occurs in the next pill-free period following the use of Levonorgestrel after regular hormonal contraception, pregnancy should be ruled out.

Repeated administration within a menstrual cycle is not advisable because of the possibility of disturbance of the cycle.

Limited and inconclusive data suggest that there may be reduced efficacy of Levonorgestrel with increasing body weight or body mass index (BMI). In all women, emergency contraception should be taken as soon as possible after unprotected intercourse, regardless of the woman's body weight or BMI.

Levonorgestrel is not as effective as a conventional regular method of contraception and is suitable only as an emergency measure. Women who present for repeated courses of emergency contraception should be advised to consider long-term methods of contraception.

Use of emergency contraception does not replace the necessary precautions against sexually transmitted diseases.

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.

Medicines containing levonorgestrel may increase the risk of cyclosporin toxicity due to possible inhibition of cyclosporin metabolism.

PREGNANCY AND LACTATION

Pregnancy
Levonorgestrel 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 fetus but there are no clinical data on the potential consequences if doses greater than 1.5 mg of levonorgestrel are taken.

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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 at least following Levonorgestrel administration.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

No studies on the effect on the ability to drive and use machines have been performed.

UNDESIRABLE EFFECTS

Headache, Dizziness, Nausea, Lower abdominal pain, Diarrhoea, Vomiting, Bleeding not related to menses, Delay of menses more than 7 days, Irregular menstruation, Breast tenderness, Fatigue,

OVERDOSE

Serious undesirable 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.

PHARMACODYNAMIC

A synthetic progestational hormone with actions similar to those of progesterone and about twice as potent as its racemic or (+-)-isomer (norgestrel). Binds to the progesterone and estrogen receptors. Target cells include the female reproductive tract, the mammary gland, the hypothalamus, and the pituitary. Once bound to the receptor, progestins like levonorgestrel will slow the frequency of release of gonadotropin releasing hormone (GnRH) from the hypothalamus and blunt the pre-ovulatory LH (luteinizing hormone) surge.

PHARMACOKINETIC

Absorption

Orally administered levonorgestrel is rapidly and almost completely absorbed.

Distribution

The results of a pharmacokinetic study carried out with 16 healthy women showed that following ingestion of one tablet of Levonorgestrel maximum drug serum levels of levonorgestrel of 18.5ng/ml were found at 2 hours. After reaching maximum serum levels, the concentration of levonorgestrel decreased with a mean elimination half-life of about 26 hours.

Metabolism

Levonorgestrel is not excreted in unchanged form but as metabolites.

Elimination

Levonorgestrel metabolites are excreted in about equal proportions with urine and faeces. The biotransformation follows the known pathways of steroid metabolism, the levonorgestrel is hydroxylated in the liver and the metabolites are excreted as glucuronide conjugates.

No pharmacologically active metabolites are known.

STORAGE CONDITIONS

Store below 30°C, protected from light & moisture.
Keep all medicines out of reach of children.

PACK PRESENTATION

1 Tablet packed in Blister.

Product from

Unosource Pharma Ltd.

Manufactured by:
Akums Drugs & Pharmaceuticals Ltd.
47,48, Sector-6A, I.I.E., SIDCUL,
Ranipur, Haridwar-249 403, INDIA.

250 mm