SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT:

UNOSURE 72 (Levonorgestrel Tablets BP)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION:

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

For a full list of excipients, see Section 6.1.

3. PHARMACEUTICAL FORM:

Pink coloured, round, boconvex film coated tablets.

4. CLINICAL PARTICULARS:

4.1. Therapeutic Indications:

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

4.2. Posology and method of 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.

4.3. Contraindications:

Hypersensitivity to the active substance.

4.4. Special warnings and precautions for use:

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.

This medicinal product contains lactose monohydrate. Patients with rare hereditary problems of galactose intolerance, total lactose deficiency or glucose-galactose malabsorption should not take this medicine.

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.

4.5. Interation with other medicinal products and other forms of 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.

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

Breastfeeding
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 8 hours following Levonorgestrel administration.

4.7. Effects on ability to drive and use machine:
No studies on the effect on the ability to drive and use machines have been performed.

4.8. Undesirable effects:
The most commonly reported undesirable effect was nausea.

System Organ Class	**Frequency of adverse reactions**	
	Very common (≥1/10)	**Common (≥1/100 to <1/10)**
Nervous system disorders	Headache	Dizziness
Gastrointestinal disorders	Nausea Abdominal pain lower	Diarrhoea Vomiting
Reproductive system and breast disorders	Bleeding not related to menses	Delay of menses more than 7 days Menstruation irregular Breast tenderness
General disorders and administration site condition	Fatigue	

From Post-marketing surveillance study of Levonorgestrel tablets, the following additional adverse events have been reported:

Gastrointestinal disorders
Very rare (<1/10,000): abdominal pain

Skin and subcutaneous tissue disorders
Very rare (<1/10,000): rash, urticarial, pruritis

Reproductive system and breast disorders
Very rare (<1/10,000): penvic pain, dysmenorrhoea

General disorders and administration site conditions
Very rare (<1/10,000): face oedema

4.9. Overdosage:
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.

5. PHARMACOLOGICAL PROPERTIES:

5.1. Pharmacodynamics Properties:

Pharmacotherapeutic group: Sex hormones and modulators of the genital system, emergency contraceptives, ATC code: G03AD01.

Mechanism of action
At the recommended regime, Levonorgestrel is thought to work mainly by preventing ovulation and fertilisation if intercourse has taken place in the pre ovulatory phase, when the likelihood for fertilisation is the highest, Levonorgestrel is not effective once the process of implantation has begun.

At the recommended regime, Levonorgestrel is not expected to induce significant modification of blood clotting factors, lipid and carbohydrate metabolism.

Paediatric population:
A prospective observational study showed that the failure rate in women under 18 years (2.6% or 4/153) was comparable to the failure rate in woman 18 years and above (2.0% or 3/152).

5.2. Pharmacokinetic Properties:

Absorption:
Orally administered Levonorgestrel is rapidly and almost completely absorbed. The absolute bioavailability of Levonorgestrel was determined to be almost 100% of the dose administered.

Distribution:
Levonorgestrel is bound to serum albumin and sex hormone binding globulin (SHBG). Only about 1.5% of the total serum levels are present as free steroid, but 65% are specifically bound to SHBG.
About 0.1% of the material dose can be transferred via milk to the nursed infant.

Biotransformation:
The biotransformation follows the known pathways of steroid metabolism, the Levonorgestrel is hydroxylated by liver enzymes mainly by CYP3A4 and its metabolites are excreted after glucuronidation by liver glucuronidase enzymes.
No pharmacologically active metabolites are known.

Elimination:
After reaching maximum serum levels, the concentration of Levonorgestrel decreased with a mean elimination half-life of about 26 hours. Levonorgestrel is not excreted in unchanged from but as metabolites. Levonorgestrel metabolites are excreted in about equal proportions with urine and faeces.

5.3. Preclinical safety data:
Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeat-dose toxicity, genotoxicity, carcinogenicity.

6. PHARMACEUTICAL PARTICULARS:
6.1. List of Excipients:

Lactose BP, Starch BP, Polyvinyl Pyrrolidone (PVPK 30) BP, Colloidal Anhydrous Silica BP, Magnesium Stearate BP, Hypromellose (HPMC) BP, Polyethylene Glycol BP, Titanium Dioxide BP, Purified Talc BP, Colour Erythrosine Lake & Colour Indigo Carmine Lake.

6.2. Incompatibilities:
Not applicable

6.3. Shelf Life:
36 Months

6.4. Special Precautions For Storage:
Store below 30ºC, protected from light & moisture.

6.5. Nature and contents of container:
One tablet is packed in Alu-PVC blister and one such blister of one tablet is packed in carton along with packaging insert.

6.6. Special precaution for disposal:
No special precaution required.

7. MARKETING AUTHORIZATION HOLDER:
Unosource Pharma Ltd.
503-504, 5th Floor Hubtown Solaris
N.S. Phadke Marg, Andheri (East) MumbaI-400069, India

8. MARKETING AUTHORISATION NUMBER(S):
05538/0806/NMR/2020

9. DATE OF FIRST AUTHORIZATION/RENEWAL OF THE AUTHORIZATION:
11-12-2020

10. DATE OF REVISION OF THE TEXT:
07-07-2023