

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1.0 NAME OF THE MEDICINAL PRODUCT**

**1.1 Product name:** UNOSURE 72

**1.2 Strength:**

Each film-coated tablet contains:

Levonorgestrel Tablets BP ..... 1.5 mg

**1.3 Pharmaceutical form:** Oral Tablets

### **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 full list of excipients, see section 6.1 of SmPC

### **3. PHARMACEUTICAL FORM**

Film coated tablet

Pink coloured, round, biconvex 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.

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 bodyweight 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 contra-ception should be

advised to consider long-term methods of contra-ception.

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

#### **4.5 Interaction with other medicinal products and other forms of interaction**

The metabolism of Levonorgestrel is enhanced by con-comitant 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 Fertility, 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.

##### **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.

#### **4.7 Effects on ability to drive and use machines**

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

#### **4.8 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.

Reporting of suspected adverse reactions: Healthcare professionals are requested to report any suspected adverse reactions via pharmacy and poisons board, Pharmacovigilance Reporting System (PvERS)

<https://pv.pharmacyboardkenya.org>

#### **4.9 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.

### **5.0 PHARMACOLOGICAL PROPERTIES**

#### **5.1 Pharmacodynamic Properties**

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.

## **5.2 Pharmacokinetic properties**

### **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.

## **5.3 Preclinical safety data**

Animal experiments with levonorgestrel have shown virilisation of female fetuses at high doses.

Pre-clinical data from conventional studies on chronic toxicity, mutagenicity and carcinogenicity reveal no special hazard for humans potential.

## **6. PHARMACEUTICAL PROFILES**

### **6.1 List of excipients**

Dichloromethane BP

Isopropyl Alcohol BP

Lactose Monohydrate BP

Starch BP

Polyvinyl Pyrrolidone BP

Colloidal Anhydrous Silica

Magnesium Stearate BP

Hypromellose BP

Polyethylene Glycol BP

Titanium Dioxide BP

Purified Talc BP

Col. Erythrosine Lake

Col. Indigo Carmine Lake

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf Life**

36 months

### **6.4 Special precautions for storage**

Store below 30°C. Protect from light & moisture.

Keep out of reach of children.

**6.5 Nature and contents of container**

1 Tablet packed in Alu-PVC blister in printed carton along with pack insert.

**6.6 Special precautions for disposal**

Not Applicable.

**7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES**

**MAH:**

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**8. MARKETING AUTHORIZATION NUMBER**

H2024/CTD10880/24028

**9. DATE OF FIRST REGISTRATION / RENEWAL OF THE REGISTRATION**

22 May 2024

**10. DATE OF REVISION OF THE TEXT**