# SUMMARY OF PRODUCT CHARACTERISTICS
## HERNEE 2 (Levonorgestrel Tablets BP 0.75 mg)

## 1. NAME OF THE MEDICINAL PRODUCT

HERNEE 2 (Levonorgestrel Tablets BP 0.75 mg)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each film-coated tablet contains levonorgestrel BP 0.75 mg.

**Excipients with known effect:**

Contains lactose (as lactose monohydrate), indigo, carmine lake and erythrosine lake. For warnings, see section 4.4.

For a full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Film-coated tablet.

Film-coated tablet.

## 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

**Posology**

For oral administration. The treatment course comprises two tablets. The highest efficacy is achieved if the first tablet is taken as soon as possible (and no later than 72 hours) after unprotected intercourse. The second tablet should be taken 12 hours (and no later than 16 hours) after the first tablet. HERNEE 2 can be used at any time during the menstrual cycle unless menstrual bleeding is overdue.

If vomiting occurs within 3 hours of taking a tablet, another tablet should be taken immediately. If repeated vomiting occurs, the tablet may be administered vaginally.

Women who have used enzyme-inducing drugs during the last 4 weeks are recommended to take a double dose of levonorgestrel (i.e. 2 tablets taken together, followed by 2 tablets taken 12 hours later).

After using emergency contraception, a local barrier method should be used (condom, diaphragm, spermicide, cervical cap) until the next menstrual period. HERNEE 2 does not contraindicate continuation of regular hormonal contraception.

**Paediatric population**

HERNEE 2 is not recommended for use by young women aged under 16 years without medical supervision.

**Method of administration**

Oral.

### 4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

**General**

Emergency contraception is an occasional method; it should not replace a regular contraceptive method. Emergency contraception does not prevent a pregnancy in every instance. If there is uncertainty about the timing of unprotected intercourse or if the woman has had unprotected intercourse more than 72 hours earlier in the same menstrual cycle, efficacy may be reduced.

**Ectopic pregnancy**

If pregnancy occurs after treatment, the possibility of an ectopic pregnancy must be considered. The absolute risk of ectopic pregnancy is likely low, as levonorgestrel prevents ovulation and fertilisation, but ectopic pregnancy may continue despite uterine bleeding. Levonorgestrel is not recommended for patients at risk of ectopic pregnancy (previous salpingitis or ectopic pregnancy).

**Menstrual cycle effects**

After levonorgestrel intake, menstrual periods are usually normal and occur at the expected date; they can sometimes occur a few days earlier or later. If the next menstrual period is more than 5 days overdue or abnormal, pregnancy should be excluded. Repeated administration within a menstrual cycle is inadvisable due to the possibility of cycle disturbance.

**Hepatic dysfunction**

Levonorgestrel is not recommended in patients with severe hepatic dysfunction.

**Malabsorption syndromes**

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

**Body weight / BMI**

Limited and inconclusive data suggest there may be reduced efficacy with increasing body weight or BMI. In all women, emergency contraception should be taken as soon as possible after unprotected intercourse, regardless of body weight or BMI.

**Sexually transmitted infections**

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

**Lactose content**

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

**Azo/xanthene dye content**

This product contains indigo carmine lake (E132) and erythrosine lake (E127). These colouring agents may cause allergic reactions.

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

The metabolism of levonorgestrel is enhanced by concomitant use of CYP3A4 enzyme inducers. Concomitant administration of efavirenz has been found to reduce plasma levels of levonorgestrel (AUC) by approximately 50%.

Drugs suspected of reducing levonorgestrel plasma levels include: barbiturates (including primidone), phenytoin, carbamazepine, Hypericum perforatum (St. John's Wort), rifampicin, ritonavir, rifabutin and griseofulvin. For women who have used enzyme-inducing drugs in the past 4 weeks, a copper IUD is the preferred option for emergency contraception. Taking a double dose of levonorgestrel is an option for women who are unable or unwilling to use a Cu-IUD, although this specific combination has not been formally studied.

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

## 4.6 Fertility, pregnancy and lactation

**Pregnancy**

Levonorgestrel should not be given to pregnant women and will not interrupt a pregnancy. In the case of continued pregnancy, limited epidemiological data indicate no adverse effects on the foetus.

**Breast-feeding**

Levonorgestrel is secreted into breast milk. Potential exposure of an infant can be reduced if the breast-feeding woman takes the tablet immediately after feeding and avoids nursing for at least 8 hours following levonorgestrel administration.

**Fertility**

Although there are no long-term fertility data, a rapid return to fertility is expected after treatment. Regular contraception should be continued or initiated as soon as possible.

## 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

**Summary of the safety profile**

The most commonly reported undesirable effect was nausea. The following table lists adverse drug reactions by system organ class and frequency.

| System Organ Class | Very common (≥1/10) | Common (≥1/100 to <1/10) |
|---|---|---|
| Nervous system disorders | Headache | Dizziness |
| Gastrointestinal disorders | Nausea, lower abdominal pain | Diarrhoea, vomiting |
| Reproductive system and breast disorders | Bleeding not related to menses | Delay of menses >7 days, irregular menstruation, breast tenderness |
| General disorders | Fatigue | |

*Post-marketing — Very rare (<1/10,000): abdominal pain; rash, urticaria, pruritus; pelvic pain, dysmenorrhoea; face oedema.*

**Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via the National Regulatory Authority.

### 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. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

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

At the recommended regimen, levonorgestrel is thought to work mainly by preventing ovulation and fertilisation if intercourse has taken place in the preovulatory phase. Levonorgestrel is not effective once the process of implantation has begun. At the recommended regimen, levonorgestrel is not expected to induce significant modification of blood clotting factors or lipid and carbohydrate metabolism.

Results from randomised, double-blind clinical studies (WHO, 1998, 2002, 2010) showed that levonorgestrel 1,500 µg (taken within 72 hours of unprotected sex as two 0.75 mg doses 12 hours apart, or as a single dose) prevented 85–97% of expected pregnancies. The meta-analysis pregnancy rate was 1.01% (59/5,863) compared with an expected rate of approximately 8% in the absence of emergency contraception. Efficacy appears to decrease with increasing time from unprotected intercourse; the highest efficacy is reached when EC is taken within 24 hours.

Data on the effect of body weight or BMI on efficacy are limited and inconsistent: the WHO meta-analysis showed no trend of reduced efficacy with increasing BMI, while two other studies reported reduced efficacy in obese women.

### 5.2 Pharmacokinetic properties

**Absorption**

Orally administered levonorgestrel is rapidly and almost completely absorbed. Absolute bioavailability is approximately 100%. Following ingestion of levonorgestrel 1.5 mg as a single tablet, maximum serum levels of approximately 18.5 ng/ml were found at 2 hours.

**Distribution**

Levonorgestrel is bound to serum albumin and sex hormone binding globulin (SHBG). Only approximately 1.5% of total serum levels are present as free steroid; 65% are specifically bound to SHBG. Approximately 0.1% of the maternal dose can be transferred via milk to the nursing infant.

**Biotransformation**

Levonorgestrel is hydroxylated by liver enzymes mainly by CYP3A4; metabolites are excreted after glucuronidation. No pharmacologically active metabolites are known.

**Elimination**

After reaching maximum serum levels, levonorgestrel concentration decreases with a mean elimination half-life of approximately 26 hours. Metabolites are excreted in approximately equal proportions in urine and faeces.

**Pharmacokinetics in obese women**

A pharmacokinetic study showed levonorgestrel concentrations are decreased in obese women (BMI ≥30 kg/m²) by approximately 50% in Cmax and AUC0-24 compared to women with normal BMI (<25 kg/m²). Doubling the dose in obese women appeared to provide plasma concentration levels similar to those in normal-weight women receiving 1.5 mg. The clinical relevance is unclear.

### 5.3 Preclinical safety data

Animal experiments with levonorgestrel have shown virilisation of female foetuses at high doses. Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeat-dose toxicity, genotoxicity and carcinogenicity potential.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

| No. | Excipient |
|---|---|
| 1 | Maize starch |
| 2 | Lactose monohydrate (excipient with known effect) |
| 3 | Crospovidone |
| 4 | Povidone |
| 5 | Colloidal anhydrous silica |
| 6 | Magnesium stearate |
| 7 | Super Coat (film coat — IH) |
| 8 | Titanium dioxide (E171) |
| 9 | Purified talc |
| 10 | Isopropyl alcohol |
| 11 | Methylene dichloride |
| 12 | Indigo carmine lake (E132) (excipient with known effect) |
| 13 | Erythrosine lake (E127) (excipient with known effect) |

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

36 months.

### 6.4 Special precautions for storage

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

### 6.5 Nature and contents of container

2 tablets packed in one ALU-PVC blister; 1 such blister packed in a carton with package leaflet. Pack size: 2 tablets.

### 6.6 Special precautions for disposal and other handling

Any unused medicine or waste material should be disposed of in accordance with local requirements.

## 7. MARKETING AUTHORISATION HOLDER

**NATIONAL PHARMACY LTD**

Colchester Park, P.O. Box 17843-00500, Nairobi, Kenya.

## 8. MARKETING AUTHORISATION NUMBER (PPB REGISTRATION NUMBER)

H2026/CTD12252/25983

## 9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

15.03.2026

## 10. DATE OF REVISION OF THE TEXT

15.03.2026