Summary of Product Characteristics
CANADIL
(Clotrimazole 100 mg vaginal tablets)

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1. Name of the medicinal product

CANADIL (Clotrimazole Vaginal Tablets 100 mg)

2. Qualitative and quantitative composition

Each uncoated vaginal tablet contains 100 mg of clotrimazole.

For the full list of excipients, see section 6.1.

3. Pharmaceutical form

Vaginal tablet.

Off-white, oblong-shaped uncoated vaginal tablet.

4. Clinical particulars

4.1 Therapeutic indications

Clotrimazole vaginal tablets are indicated for the treatment of candidal vaginitis.

4.2 Posology and method of administration

Posology

One vaginal tablet is inserted at night, using the applicator provided. A second course may be carried out if necessary.

Method of administration

One 100 mg tablet is placed into the holder of the applicator, which is inserted as high as possible into the vagina, preferably at bedtime while lying back with the legs bent up. Treatment should not be carried out during menstruation and should be completed before its onset. Tampons, intravaginal douches, spermicides or other vaginal products should not be used during treatment, and vaginal intercourse should be avoided while there is a vaginal infection and during use. When used in pregnancy, the tablet should be inserted without the applicator. Not for use in children under 16 years.

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

Medical advice should be sought if this is the first episode of candidal vaginitis, or if any of the following apply: more than two infections in the last 6 months; a previous history of, or exposure to a partner with, a sexually transmitted disease; pregnancy or suspected pregnancy; age under 16 or over 60 years; or known hypersensitivity to imidazoles or other vaginal antifungals. Medical advice should also be sought in the presence of irregular or abnormal vaginal bleeding, a blood-stained discharge, vulval or vaginal ulcers, blisters or sores, lower abdominal pain or dysuria, fever or chills, nausea or vomiting, diarrhoea, or a foul-smelling discharge. Patients should consult their physician if symptoms are not relieved within one week, or if the infection recurs more than twice

within six months. The tablets need moisture in the vagina to dissolve completely; inserting the tablet high into the vagina at bedtime helps prevent undissolved fragments.

4.5 Interaction with other medicinal products and other forms of interaction

This product may damage latex contraceptives, reducing their effectiveness; alternative precautions should be used for at least five days after use. Concomitant vaginal clotrimazole with oral tacrolimus or sirolimus might lead to increased plasma levels of these agents; patients should be monitored for signs of overdosage.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are limited data from the use of clotrimazole in pregnant women. At the low systemic exposure following vaginal treatment, harmful effects are not predicted. Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife, and the tablet should be inserted without the applicator.

Breast-feeding

Systemic absorption is minimal and unlikely to lead to systemic effects; clotrimazole may be used during lactation.

Fertility

Animal studies have not demonstrated any effect of clotrimazole on fertility.

4.7 Effects on ability to drive and use machines

This medicine has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

The adverse reactions listed below are based on spontaneous reports, and so assigning an accurate frequency is not possible; all are of frequency ‘not known’.

System Organ Class	Frequency	Adverse reaction
Immune system disorders	Not known	Anaphylactic reaction, angioedema, hypersensitivity
Vascular disorders	Not known	Syncope, hypotension
Respiratory, thoracic and mediastinal disorders	Not known	Dyspnoea
Gastrointestinal disorders	Not known	Abdominal pain, nausea
Skin and subcutaneous tissue disorders	Not known	Rash, urticaria, pruritus
Reproductive system and breast disorders	Not known	Vaginal exfoliation, vaginal discharge, vaginal haemorrhage, vulvovaginal discomfort, erythema, burning sensation, pruritus and pain
General disorders and administration site conditions	Not known	Application-site irritation, oedema and pain

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 to the National Regulatory Authority.

4.9 Overdose

No risk of acute intoxication is expected following a single vaginal or dermal overdose, or inadvertent oral ingestion. There is no specific antidote. In the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if clinical symptoms of overdose (e.g. dizziness, nausea or vomiting) become apparent and the airway can be adequately protected.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Gynaecological anti-infectives and antiseptics, imidazole derivatives. ATC code: G01AF02.

Clotrimazole acts against fungi by inhibiting ergosterol synthesis, leading to structural and functional impairment of the fungal cytoplasmic membrane. It has a broad antimycotic spectrum in vitro and in vivo that includes dermatophytes, yeasts and moulds; its action is fungistatic or fungicidal depending on the concentration at the site of infection. Primary resistance of sensitive fungal species is very rare.

5.2 Pharmacokinetic properties

After vaginal application only a small amount of clotrimazole (3–10% of the dose) is absorbed, and rapid hepatic metabolism into inactive metabolites results in peak plasma levels below 10 ng/mL, demonstrating that intravaginal clotrimazole does not lead to measurable systemic effects. Binding to serum proteins is about 98%. The elimination half-life is 3.5–5 hours, with metabolites excreted mainly via the bile in the faeces.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated-dose toxicity, genotoxicity and carcinogenicity. Clotrimazole was not teratogenic in mice, rats and rabbits, although high oral doses in rats were associated with maternal toxicity, embryotoxicity, reduced foetal weights and decreased pup survival.

6. Pharmaceutical particulars

6.1 List of excipients

- Maize starch
- Dibasic calcium phosphate
- Microcrystalline cellulose
- Povidone (PVP K-30)
- Purified talc
- Magnesium stearate
- Sodium starch glycolate
- Colloidal silicon dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store in a cool, dry place. Protect from light. Keep out of the reach and sight of children.

6.5 Nature and contents of container

6 tablets in an Alu-Alu strip, presented in a carton together with an applicator and the package insert.

6.6 Special precautions for disposal and other handling

Wash your hands before and after handling the applicator and blister pack.

Any unused medicinal product 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

9705-4998

9. Date of first authorisation / renewal of the authorisation

10. Date of revision of the text