

SUMMARY OF PRODUCT CHARACTERISTICS

IMAZOLE V

Clotrimazole Pessaries BP 100 mg

1. NAME OF THE MEDICINAL PRODUCT

IMAZOLE V

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Pessary contains Clotrimazole BP 100 mg

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Pessary

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

IMAZOLE V is recommended for the treatment of candidal vaginitis.

4.2 Posology and method of administration

The pessaries should be inserted into the vagina, as high as possible, using the applicator provided. This is best achieved when lying back with legs bent up.

Adults:

Two pessaries should be inserted daily (preferably at night) for three consecutive days. Alternatively, one pessary may be inserted daily for six days, preferably at night. A second treatment may be carried out if necessary.

There is no separate dosage schedule for the elderly.

Canesten pessaries need moisture in the vagina in order to dissolve completely, otherwise undissolved pieces of the pessary might crumble out of the vagina. Pieces of undissolved pessary may be noticed by women who experience vaginal dryness. To help prevent this it is important that the pessary is inserted as high as possible into the vagina at bedtime.

Generally:

Treatment during the menstrual period should not be performed due to the risk of the pessary being washed out by the menstrual flow. The treatment should be finished before the onset of menstruation.

Do not use tampons, intravaginal douches, spermicides or other vaginal products while using this product.

Vaginal intercourse should be avoided in case of vaginal infection and while using this product because the partner could become infected.

Children:

Not for use in children under 16.

4.3 Contraindications

Hypersensitivity to Clotrimazole or any ingredient in this medicine.

4.4 Special warnings and precautions

Medical advice should be sought if this is the first time the patient has experienced symptoms of candidal vaginitis.

Before using IMAZOLE V Pessaries, medical advice must be sought if any of the following are applicable:

- More than two infections of candidal vaginitis in the last 6 months.
- Previous history of sexually transmitted disease or exposure to partner with sexually transmitted disease.
- Pregnancy or suspected pregnancy.
- aged under 16 or over 60 years.
- known hypersensitivity to imidazoles or other vaginal antifungal products.

IMAZOLE V Pessaries should not be used if the patient has any of the following symptoms where upon medical advice should be sought:

- Irregular vaginal bleeding.
- Abnormal vaginal bleeding or a blood-stained discharge.
- Vulval or vaginal ulcers, blisters or sores.
- Lower abdominal pain or dysuria.
- Any adverse events such as redness, irritation or swelling associated with the treatment.
- Fever or chills.

- Nausea or vomiting.
- Diarrhoea.
- foul smelling vaginal discharge.

Patients should be advised to consult their physician if the symptoms have not been relieved within one week of using IMAZOLE V Pessary. IMAZOLE V Pessary can be used again if the candidal infection returns after 7 days. However, if the candidal infection recurs more than twice within six months, patients should be advised to consult their physician.

4.5 Interaction with other medicinal products and other form of interactions:

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

Concomitant medication with vaginal Clotrimazole and oral tacrolimus (FK-506; immunosuppressant) might lead to increased tacrolimus plasma levels. Patients should thus be closely monitored for signs and symptoms of tacrolimus overdose, if necessary by determination of the respective plasma levels.

4.6 Pregnancy and Lactation

Data on a large number of exposed pregnancies indicate no adverse effects of Clotrimazole on pregnancy or on the health of the foetus/newborn child. To date, no relevant epidemiological data are available.

Clotrimazole can be used during pregnancy, but only under the supervision of a physician or midwife.

4.7 Effects on Ability to Drive and Use Machines

Not applicable.

4.8 Undesirable effects:

As the listed undesirable effects are based on spontaneous reports, assigning accurate frequency of occurrence for each is not possible.

Immune system disorders:

Allergic reaction (syncope, hypotension, dyspnea, urticaria, pruritus)

Reproductive system and breast disorders:

Genital peeling, pruritus, rash, oedema, discomfort, burning, irritation, pelvic pain

Gastrointestinal disorders:

Abdominal pain

4.9 Overdose

In the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). It should be carried out only if the airway can be protected adequately.

5. PHARMACOLOGICAL PROPERTIES:

5.1 Pharmacodynamic properties:

Clotrimazole is an imidazole derivative with a broad spectrum of antimycotic activity.

Mechanism of Action

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane.

Pharmacodynamic Effects

Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc. The mode of action of Clotrimazole is fungistatic or fungicidal depending on the concentration of Clotrimazole at the site of infection. In-vitro activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive. Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

5.2 Pharmacokinetic properties:

Pharmacokinetic investigations after vaginal application have shown that only a small amount of Clotrimazole (3 – 10% of the dose) is absorbed. Due to the rapid hepatic metabolism of absorbed Clotrimazole into pharmacologically inactive metabolites the resulting peak plasma concentrations of Clotrimazole after vaginal application of a 500mg dose were less than 10 mg/ml, reflecting that Clotrimazole applied intravaginally does not lead to measurable systemic effects or side effects.

5.3 Preclinical safety data

Not Available

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Polyethylene - Glycol 1500 BP/EP

Polyethylene Glycol 6000 BP/EP

Methyl Paraben BP/EP

Propyl Paraben BP/EP

Butylated Hydroxytoluene BP/EP

6.2 Incompatibilities

Not known

6.3 Shelf Life

36 months

6.4 Special precaution for storage

Store at temperature not exceeding 30°C, Protect from light.

6.5 Nature and content of container

Imazole V Pessaries are packed in polyvinylchloride foil coated with Polyethylene.

1. A strip containing 6 Pessary is packed in one mono carton along with pack insert & Applicator.
2. A strip containing 7 Pessary is packed in one mono carton along with pack insert.