

IMAZOLE-V/IMAZOLE 200-V/IMAZOLE 500-V

(Clotrimazole Pessaries BP 100 mg/200mg/500mg)

IMAZOLE-V

Composition :

Each pessary contains :
Clotrimazole BP 100 mg
Excipients q.s.

IMAZOLE 200-V

Composition :

Each pessary contains :
Clotrimazole BP 200 mg
Excipients q.s.

IMAZOLE 500-V

Composition :

Each pessary contains :
Clotrimazole BP 500 mg
Excipients q.s.

Pharmacodynamic properties

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the fungal cytoplasmic membrane. Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc.

Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate. 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.

Pharmacokinetic properties

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

Indications:

For the treatment of Vaginal Candidiasis

SHOULD NOT BE USED FOR VULVUR ITCHING DUE TO CAUSES OTHER THAN YEAST INFECTION

Dose and Method of Administration:

Imazole-V : One Pessary to be inserted for Seven consecutive nights

Imazole 200-V : One Pessary to be inserted for Three consecutive nights

Imazole 500-V : One Pessary to be inserted at night as a single dose

Or as directed by the physician

The Pessary is to be inserted in vagina as gently and deeply in a comfortable position preferably lying on the back. In case of refractory and recurring infection the dose and/or duration may be doubled.

For better results the treatment should be commenced after menstruation or completed before the start of menstruation

Contraindications:

Imazole is contraindicated in patients with known sensitivity or allergy to Clotrimazole or other ingredients of the product. The medicine is not recommended for use in children

Precautions & Warnings:

In case of experiencing the symptoms of vaginal thrush for the first time, having more than two infections in the last six months, pregnancy, age group of under 16 or over 60 years person should make sure to consult a doctor before using this medicine.

In case of following symptoms patient should consult a physician: irregular or abnormal vaginal bleeding, blood-stained or foul-smelling vaginal discharge, vulval or vaginal ulcers, blisters or sores, lower abdominal pain, pain passing urine, fever, chills, nausea, vomiting or diarrhea. If irritation or sensitivity develops, discontinue use and institute appropriate therapy.

Pessary is not to be taken by mouth. It is for vaginal use only.

Pregnancy and Lactation:

In clinical trials, use of vaginally applied Clotrimazole in pregnant women in their second and third trimesters has not been associated with ill effects. There are no adequate and well controlled studies in pregnant women during first trimester of pregnancy.

Since very little of this medicine is absorbed into the bloodstream from the vagina it is unlikely that any of the medicine will pass into breast milk. However, Clotrimazole pessaries may be used in pregnancy and lactation only if recommended by a physician if benefits outweigh the risk.

Interactions:

There are no significant drug interactions

There is a possibility that this preparation may damage latex (rubber) condoms and diaphragms (caps) and the effectiveness of these contraceptives may consequently be reduced.

Side effects:

Since the drug is not absorbed through the vagina it is unlikely to produce systemic side effects.

Certain sight specific side effects such as vaginal itching, irritation, burning, vaginal soreness or pain during sexual intercourse may occur.

Overdose:

No risk of acute intoxication is seen as it is unlikely to occur following a single vaginal of an overdose or inadvertent oral ingestion. There is no specific antidote.

However, in the event of accidental oral ingestion, gastric lavage should be considered only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting) and the airway can be protected adequately.

Storage:

Store in the original package below 30°C. Protect from light.

Keep out of the reach and sight of children.

Presentation:

Imazole-V: Strip of 7 vaginal Pessaries in a carton along with a leaflet; Imazole 200-V: Strip of 3 vaginal Pessaries in a carton along with a leaflet; Imazole 500-V: Strip of 1 vaginal Pessary in a carton along with a leaflet.

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How to use Pessaries

1. Wash your hands.
2. Do not open pessary if it seems soft, hold the foil wrapper under cold water or place it in refrigerator for few minutes to harden it before removing the wrapper.
3. Remove one pessary from the strip and hold it in fingertips.
4. Remove any foil or plastic wrapping stuck to the pessary.
5. Sit or lie down with your knees bent and legs apart.
6. Gently insert the pessary into the vagina as far as comfortably possible using your fingers.
7. Wash your hands again.



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