

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

VAGID 100

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

White opaque bullet shaped Pessary

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

Vagid 100 is recommended for the treatment of candidal vaginitis.

4.2 Posology and method of administration

The Pessary should be inserted into the vagina, as high as possible, using the applicator provided.

Insert one pessary daily, as gently and deeply as comfortably possible into the vagina, preferably at night, for three days.

Adults over 60 years and children under 16 years of age should consult their doctor before using this medicine.

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 Vagid 100 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.

Vagid 100 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 Vagid 200 Pessary. Vagid - 200 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/ new-born 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 200mg 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

Hard Fat BP/Ph.Eur

6.2 Incompatibilities

Not known

6.3 Shelf Life

24 months

6.4 Special precaution for storage

Store in dry place, below 30°C. Protected from light.

6.5 Nature and content of container

Vagid 100 Pessaries are packed in polyvinylchloride foil coated with Polyethylene. One strip containing 7 Pessaries is packed in one mono carton along with pack insert.

7. MARKETING AUTHORIZATION HOLDER:

BLISS GVS PHARMA LIMITED

102, Hyde Park, Saki-Vihar road,

Andheri (East) Mumbai 400 072

INDIA

8. MARKETING AUTHORIZATION NUMBER

05094/06684/NMR/2018

9. DATE OF AUTHORIZATION

Apr 6, 2020