

## **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 Pessary should be inserted into the vagina, as high as possible, 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 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, Polyethylene Glycol -6000, Methyl Paraben, Propyl Paraben, Butylated Hydroxytoluene

### **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. A strip containing 7 Pessary is packed in one mono carton along with pack insert.

## **7. MARKETING AUTHORISATION HOLDER**

Bliss GVS Pharma Ltd.,  
102, Hyde Park, Saki vihar Road,  
Andheri (E), Mumbai-400 072