

SUMMARY OF PRODUCT CHARACTERISTIC

POVID

(Povidone Iodine Pessaries 200 mg)

1. Name of the medicinal product

POVID (Povidone Iodine Pessaries 200 mg)

2. Qualitative and quantitative composition

Each pessary contains

Povidone Iodine (Available Iodine 20 mg) USP 200 mg

Excipients (QS)

For the full list of excipients see section 6.1

3. Pharmaceutical form

Pessary.

Brown bullet shaped Pessaries

4. Clinical particulars

4.1 Therapeutic indications

POVID is used for the treatment of vaginitis caused by

- Candida albicans (Candidiasis or Moniliasis)
- Trichomonas vaginalis (Trichomoniasis)
- Bacteria (Bacterial or formerly known as Non-specific vaginitis)
- Mixed Infections (Caused due to one or more organisms)

4.2 Posology and method of administration

- Insert one POVID pessary in the morning and at night for up to 14 days.
- Ideally, treatment should either end before menstrual period or start after the menses. However, if menstruation occurs during treatment it is advisable not to discontinue the treatment

4.3 Contraindications

- Hypersensitivity to iodine or any component of the preparation
- Thyroid disorders, in particular overactive thyroid (hyperthyroidism), nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis
- Scheduled radioiodine therapy
- Dermatitis herpetiformis - Duhring's disease
- Children under 8 years of age

4.4 Special warnings and precautions for use

- For vaginal use only
- Do not
 - Use in the eyes
 - Use on individuals who are allergic or sensitive to iodine
 - Apply over large areas of the body
- Keep out of reach of children
- If swallowed, get medical help immediately
- Discontinue use and ask a doctor
 - If condition persists or gets worse
 - If irritation, sensitization, or allergic reaction occurs and lasts for 72 hours. These may be signs of a serious condition.

4.5 Interaction with other medicinal products and other forms of interaction

- POVID is not incompatible with other disinfectant and antiseptic agents, particularly those containing alkali, enzymes and mercury
- Combined use of povidone iodine and hydrogen peroxide, as well as enzyme preparations containing silver and tauridin for treatment of wounds, as well as antiseptics, leads to mutual inefficiencies.
- In the presence of blood bactericidal effect can be reduced, however, by increasing the concentration, the bactericidal activity can be increased.

4.6 Pregnancy and lactation

- Povidone pessary is not recommended for use starting from the 3rd month of pregnancy and during lactation. If the therapy is necessary, the doctor decides individually on the issue of prescription of the drug.

4.7 Effects on ability to drive and use machines

- Povidone-iodine has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

- Local reactions: rarely - itching, hyperemia, hypersensitivity reactions
- In rare cases, the use of the drug may cause hypersensitivity reactions such as contact dermatitis with the formation of small red psoriasiform bullous elements. If these events occur, the use of the drug should be discontinued.
- Prolonged use of povidone-iodine can lead to absorption of significant amounts of iodine. In some cases, the development of iodine-induced hyperthyroidism has been described, especially in patients with a history of thyroid disease.

4.9 Overdose

Acute iodine intoxication is characterized by the following symptoms: Metallic taste in the mouth, excessive salivation, burning sensation or pain in the mouth or throat; irritation and swelling of the eyes; skin reactions; gastrointestinal disorders and diarrhea; renal failure and anuria; circulatory failure; laryngeal edema with secondary asphyxia, pulmonary edema, metabolic acidosis, hypernatremia.

Treatment: symptomatic and supportive therapy should be conducted with particular attention to electrolyte balance, renal and thyroid function.

5. Pharmacological properties

5.1 Pharmacodynamics properties

Povidone-iodine is an antiseptic which liberates iodine in contact with the skin. Povidone iodine is a broad spectrum anti-microbial agent with activity against a wide variety of bacteria, including acid fast bacilli and bacterial spores. It is also active against fungi, a wide range of viruses and protozoa.

5.2 Pharmacokinetic properties

Absorption is rapid, serum concentrations of total iodine and inorganic iodide are increased significantly after vaginal administration.

5.3 Preclinical safety data

There are no findings in the preclinical testing which are of relevance to the prescriber.

6. Pharmaceutical particulars

6.1 List of excipients

Polyethylene Glycol 1500, Polyethylene Glycol 6000, Methyl paraben, Propyl paraben, Butylated Hydroxy Toluene.

6.2 Incompatibilities

Not Applicable

6.3 Shelf life

36 months.

6.4 Special precautions for storage

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

6.5 Nature and contents of container

Packed in polyvinyl chloride/polyethylene foil. Strip of 1x7 pessaries is packed in a carton along with pack insert.

6.6 Special precautions for disposal and other handling

None stated.

7. Marketing authorization holder

Bliss GVS Pharma Ltd.

102, Hyde Park, Saki Vihar Road, Andheri East,

Mumbai-400072, INDIA.