

SUMMARY OF PRODUCT CHARACTERISTICS

GYNASTATIN

Nystatin Pessaries 100,000 Units

COMPOSITION

Nystatin BP 100,000 Units

4.1 Therapeutic indications

For the treatment of candidial vaginitis.

4.2 Posology and method of administration

Pessaries:

Adults including the elderly:

1 or 2 pessaries should be inserted high into the vagina for 14 consecutive nights or longer, regardless of any intervening menstrual period.

Children:

Not recommended.

Route of administration: Vaginal

4.3 Contraindications

There are no known contraindications to use of GYNASTATIN, except hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

In pregnancy, care should be taken when using an applicator to prevent the possibility of mechanical trauma.

4.5 Interaction with other medicinal products and other forms of interaction

Not known.

4.6 Pregnancy and lactation

In pregnancy, care should be taken when using the applicator provided to prevent the possibility of mechanical trauma.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None stated.

4.9 Overdose

None.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Nystatin exerts its effect by interaction with cell walls and cell membranes. Sterols present in the cell membrane are necessary for this effect. Nystatin has both fungistatic and fungicidal effects.

5.2 Pharmacokinetic properties

Nystatin is an antifungal antibiotic active against *Candida albicans* and a wide range of yeast-like fungi.

5.3 Preclinical safety data

Not applicable

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Polyethylene glycol 1500, Polyethylene glycol 6000, Methyl Paraben, Propyl Paraben
Butylated Hydroxy toluene

6.2 Incompatibilities

None known.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30°C in a dry place in well closed containers. Protect from light.

6.5 Nature and contents of container

2 Strips of 7 Pessaries in Polyvinyl Chloride / Polyethylene (PVC/PE) foil in mono carton along with product insert and applicator.

6.6 Special precautions for disposal

No special precautions. Use as directed by the physician.

7 MARKETING AUTHORISATION HOLDER

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