

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

NYSPEP/Nystatin Pessaries 100,000 Units

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Nystatin BP 105,000 Units (approx. 18.00 mg)

3 PHARMACEUTICAL FORM

Pessaries

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of candidal 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: Vagina

4.3 Contraindications

There are no known contraindications to use of NYSPES, 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

Lactose, povidone, purified water, industrial methylated spirit 99%, maize starch, sodium starch glycolate, magnesium stearate.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 25°C in a dry place in well closed containers. Protect from light.

6.5 Nature and contents of container

High density polystyrene with polythene lids and/or polypropylene containers with polypropylene or polythene lids and polyurethane foam sponge wads.

Pack sizes: 100 and 500.

6.6 Special precautions for disposal

No special precautions. Use as directed by the physician.

7 MARKETING AUTHORISATION HOLDER

Chelonia Healthcare Limited
Boumpoulinas 11, 3rd Floor
NICOSIA
CYPRUS
P.C. 1060
CYPRUS

8 MARKETING AUTHORISATION NUMBER(S)

PL 33414/0071

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