SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

<TRADE NAME> <STRENGTH> Vaginal Tablets

<REGARDING THE APPROVAL>

1. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vaginal tablet contains <STRENGTH> of nystatin.

Excipient with known effect:

<REGARDING THE APPROVAL>

For the full list of excipients, see section 6.1.

1. PHARMACEUTICAL FORM

Vaginal Tablet

<REGARDING THE APPROVAL>

1. CLINICAL PARTICULARS
   1. Therapeutic indications

For the treatment of candidal vaginitis..

* 1. Posology and method of administration

Vaginal tablet:

*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.

* 1. Contraindications

There are no known contraindications to use of nystatin vaginal tablet, except hypersensitivity to any of the ingredients..

* 1. Special warnings and precautions for use

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

* 1. Interaction with other medicinal products and other forms of interaction

Not known..

* 1. Fertility, pregnancy and lactation

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

* 1. Effects on ability to drive and use machines

None.

* 1. Undesirable effects

None stated.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via Health Product Vigilance Center; HPVC

* 1. Overdose

None.

1. PHARMACOLOGICAL PROPERTIES
   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.

* 1. Pharmacokinetic properties

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

* 1. Preclinical safety data

Not applicable.

1. PHARMACEUTICAL PARTICULARS
   1. List of excipients

<REGARDING THE APPROVAL>

* 1. Incompatibilities

None known.

* 1. Shelf life

<REGARDING THE APPROVAL>

* 1. Special precautions for storage

<REGARDING THE APPROVAL>

* 1. Nature and contents of container

<REGARDING THE APPROVAL>

* 1. Special precautions for disposal

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION HOLDER

<REGARDING THE APPROVAL>

1. MARKETING AUTHORISATION NUMBER(S)

<REGARDING THE APPROVAL>

1. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<REGARDING THE APPROVAL>

1. DATE OF REVISION OF THE TEXT1

<REGARDING THE APPROVAL>