VARDSTIN TABLETS
(Vardhman Exports),

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

VARDSTIN 500,000 IU TABLETS

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Sugar coated tablet contains:

Nystatin USP 500,000IU

Excipients with known effects:

Each tablet contains 198.767 mg of Dibasic calcium phosphate, 3.518 mg of Magnesium Stearate.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Yellow coloured, circular, biconvex, sugar coated tablets 'VARDSTIN' printed in Black ink on one side of each tablet.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Vardstin 500,000IU Tablets is indicated for

The prevention and treatment of candidal infections of the oral cavity, oesophagus and intestinal tract.

This is also provides effective prophylaxis against oral candidosis in those born of mothers with vaginal candidosis.

4.2 Posology and method of administration

Posology

For the treatment of intestinal candidiasis.

Oral dosage

Adults

The recommended dose is 500,000 to 1 million units PO 3 times daily. Treatment should be continued for at least 48 hours after clinical cure to prevent relapse.

For the treatment of cutaneous and mucocutaneous candidiasis, including candidal diaper dermatitis.

For the treatment of vulvovaginal candidiasis (VVC).

Method of Administration

Tablets should be swallowed whole with adequate fluids (at least 100ml of water) and should be taken in an upright sitting or standing position.

4.3 Contraindications

Hypersensitivity to the active substance(s) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Caution needed for pregnant, breastfeeding women and people who have any allergy.
Avoid excess dosage.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6. Fertility, Pregnancy and lactation

Pregnancy

Animal reproductive studies have not been conducted with Nystatin.

It is not known whether Nystatin can cause foetal harm when administered to a pregnant woman or can affect reproductive capacity; however absorption of nystatin from the gastro-intestinal tract is negligible. Nystatin should be prescribed during pregnancy only if the potential benefits to be derived outweigh the possible risks involved.

Breastfeeding

It is not known whether Nystatin is excreted in human milk. Although gastrointestinal absorption is insignificant, caution should be exercised when Nystatin is prescribed for a breast-feeding woman.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Nystatin is generally well tolerated by all age groups, even during prolonged use. If irritation or sensitisation develops, treatment should be discontinued. Nausea has been reported occasionally during therapy.

Large oral doses of Nystatin have occasionally produced diarrhoea, gastrointestinal distress, nausea and vomiting. Rash, including urticaria has been reported rarely. Steven-Johnson Syndrome has been reported very rarely. Hypersensitivity and angioedema, including facial oedema have been reported.

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.

4.9 Overdose

Since the absorption of Nystatin from the gastro-intestinal tract is negligible, overdosage or accidental ingestion causes no systemic toxicity. Oral doses of Nystatin in excess of 5 million units daily have caused nausea and gastrointestinal upset.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties

Pharmacotherapeutic group: Antifungal for topical use,

ATC code: D01AA01

Nystatin is a mixture of antifungal polyenes produced by the growth of certain strains of *Streptomyces noursei*, or by any other means. It consists largely of Nystatin A_1.

Nystatin is active against a wide range of yeasts and yeast-like fungi, including Candida albicans.

5.2 Pharmacokinetic properties

Nystatin is a tetraene macrolide. There is no data available on the pharmacokinetics as it is not absorbed from the gastro-intestinal tract, skin or vagina and most of the use is topical.

5.3 Preclinical safety data

No long-term animal studies have been performed to evaluate the carcinogenic potential of Nystatin. No studies have been performed to determine the mutagen city of nystatin or its effect on male or female fertility.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Diabasic Calcium Phosphate,
Maize Starch,
P.V.P.K.-30,
Methyl Paraben,
Propyl Paraben,
Purified Talc,
Magnesium Stearate,
Bleach Shellac,
Calcium Carbonate Heavy,
Gelatin,
Gum Accecia,
Sugar,
Titanium dioxide,
Colour Tartrazine Supra,
Titanium Dioxide,
Carnuaba wax.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store in a cool place and protect from light. Keep all medicines out of reach of children.

6.5 Nature and contents of container

PACK TYPE I: 100 tablets sealed in a PP bag printed with VARDHMAN and packed in a 200ml white plastic container sealed with white cap having two silica bag and a literature.

PACK TYPE II: 10 tablets blistered in a blister with printed aluminium foil and dark amber PVC. Such 10 blister packed in a carton with one literature.

6.6 Special precautions for disposal and other handling

No special requirements.

7. APPLICANT/MANUFACTURER

NAME & ADDRESS:

VARDHMAN EXPORTS

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