SM PHARMACEUTICALS SDN. BHD.

NYASTAT TABLET 500,000IU

DESCRIPTION:
Orange colour, round and sugar coated tablet.

NAME(S) AND STRENGTH(S) OF ACTIVE INGREDIENT(S):
Each sugar coated tablet contains: Nystatin 500,000 IU

ACTIONS AND MODE OR MECHANISMS OF ACTION:
Nystatin is a polyene antibiotic with antifungal activity against a wide variety of yeast-like fungi. Produced by a strain of *Streptomyces noursei*, nystatin is the first well-tolerated antifungal antibiotic of dependable efficacy for the treatment of oral, cutaneous, vaginal and intestinal infections caused by *Candida (Monilia) albicans* and other *Candida* sp.
Nystatin has been found to inhibit the growth of yeast-like flora in the intestinal tract. When given orally it reduces the candidal count in stools. The antibiotic exhibits no appreciable activity against bacteria.
Nystatin binds to sterols in the fungal cell membrane, resulting in the cell membrane's inability to function as a selective barrier, thus allowing loss of essential cellular constituents.

PHARMACOLOGY (SUMMARY OF PHARMACODYNAMICS AND PHARMACOKINETICS):
Absorption: Not absorbed from the gastrointestinal tract.
Saliva concentrations
Saliva concentrations of nystatin are maintained above those required *in vitro* to inhibit the growth of clinically significant *Candida* species for approximately 2 hours after the start of oral dissolution of 2 nystatin lozenges (400,000 units).
Elimination
Faecal. Orally administered nystatin is excreted almost entirely as unchanged drug.

INDICATIONS:
Nystatin oral tablets are indicated for the treatment of intestinal candidiasis.

CONTRAINDICATIONS:
Prior history of allergic reaction on exposure to Nystatin.

SIDE EFFECTS / ADVERSE REACTIONS:
Nystatin is generally well tolerated by all age groups, even during prolonged use. Rarely, oral irritation or sensitisation may occur. 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.

PRECAUTIONS / WARNINGS:
Animal reproductive studies have not been conducted with nystatin.

This medication is not to be used for the treatment of systemic mycoses. Discontinue treatment if sensitisation or irritation is reported during use.
The doctor must confirm his initial diagnosis by performing further tests for intestinal candidiasis before prescribing Nystatin Tablet.
Use in pregnancy
It is not known whether nystatin can cause foetal harm when administered to a pregnant women, 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.
Breast-feeding
Though gastro-intestinal absorption is insignificant, it is not known whether nystatin is excreted in human breast milk and caution should be exercised when nystatin is prescribed for nursing women.
The Elderly
No dosage adjustment is required in elderly patients.

DRUG INTERACTIONS:
No interactions have been described.
RECOMMENDED DOSAGE, DOSAGE SCHEDULE AND ROUTE OF ADMINISTRATION:
The usual therapeutic dose is 1 tablet (500,000 units) 3 times daily. This dosage may be increased to 2 tablets (100,000 units) 3 times daily, if intestinal fungi are not adequately suppressed.
When given concomitantly with an oral antibacterial agent, the tablets should be continued for at least as long as the antibacterial agent. Treatment should generally be continued for at least 48 hours after clinical cure to prevent relapse.

SYMPTOMS AND TREATMENT FOR OVERDOSE, AND ANTIDOTE(S):
Since the absorption of nystatin from the gastrointestinal tract is negligible, over-dosage or accidental ingestion causes no systemic toxicity.
Oral doses of nystatin in excess of 5 million units daily have caused nausea and gastrointestinal upset.

PACKING / PACK SIZES:
Strip pack of 10 tablets, 10 x 10's/Box and 100 tablets (for export only).

STORAGE CONDITIONS, USER INSTRUCTIONS AND PHARMACEUTICAL PRECAUTIONS:
Store below 30°C. Protect from light.
Auxiliary labelling
Continue medicine for full time of treatment.

SHELF LIFE: 3 years
NAME AND ADDRESS OF MANUFACTURER AND DISTRIBUTOR IN MALAYSIA:
SM PHARMACEUTICALS SDN BHD (218620-M)
Lot 88, Sungai Petani Industrial Estate
08000 Sungai Petani, Kedah, Malaysia.
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