Registration & Regulatory Affairs (R & R) Directorate

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC) TEMPLATE

1.3Product Information
1.3.1 SPC, Labeling and Package Leaflet

SPC-Summary of Product Characteristics
Route of Administration: Oral Tablets

SPC-Summary of Product Characteristics

1. Name of the Medicinal Product
Nystatin Tablets BP 500000IU

2. Qualitative and Quantitative Composition
Composition:
Each film coated tablet contains:
Nystatin BP 500000IU
Excipients: Q.S.
Colour: Titanium Dioxide

3. Pharmaceutical Form
Film coated tablet
Nystatin tablets BP 500000 IU are White colored round biconvex shaped film coated tablet having both side plain of each tablet

4. Clinical Particulars
4.1 Therapeutic Indications
Nystatin is used at candidosis of mucous tunic of oral cavity, genital organs, gastrointestinal tract, skin. With the aim of prophylactics Nystatin is prescribed for prevention of candidosis for long-term treatment with antibacterial agents, especially for emaciated and weakened patients.

4.2 Posology and Method of Administration
Nystatin is taken irrespective of food intake. Nystatin tablets are swallowed without chewing. Adults are prescribed in dosage of 500000 UNITS 3-4 times a day. Daily dose of preparation is from 1500000 to 3000000 UNITS. At generalized candidosis daily dose may be increased to 4000000-6000000 UNITS.
Children under 1 year are prescribed in dosage of 100000-125000 UNITS 3-4 times a day, from 1 year to 3 years – in dosage of 250000 UNITS 3-4 times a day, over 13 year – in dosage of 250000-500000 UNITS 3-4 times a day.
Duration of treatment course is 10-14 days. If necessary, the course of medical treatment may be repeated in a week.

4.3 Contraindications
Increased individual sensitivity to the preparation, compromised liver function, pancreatitis. gastric and duodenal ulcer, pregnancy, lactation (it is required to inhibit breast-feeding).

4.4 Special Warnings and Precautions for use

Before taking nystatin, tell your doctor or pharmacist if you are allergic to it; or if you have any other allergies. This product may contain inactive ingredients, which can cause allergic reactions or other problems. Talk to your pharmacist for more details.

Before using this medication, tell your doctor or pharmacist your medical history, especially of: HIV disease, diabetes, kidney disease.

This medication should be used only when clearly needed during pregnancy. Discuss the risks and benefits with your doctor.

It is not known whether this drug passes into breast milk. Consult your doctor before breast-feeding.

4.5 Interactions with other medicinal products and other forms of interactions
At simultaneous using of Nystatin with clotrymasol the activity of the latter is lowered.

4.6 Fertility, Pregnancy and Lactation

There are no adequate studies done with nystatin to determine safe and effective use in **pregnant** women.

It is not known whether nystatin enters **breast milk**; therefore, it is best for **nursing** mothers to be cautious before **breastfeeding**.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable Effects
Using of Nystatin may cause nausea, vomiting, diarrhea, abdominal pains, allergic reactions such as skin itch and appearance of skin rash, fever, febrile chill.
In such cases dose should be reduced or the drug should be temporarily withdrawn.

4.9 Overdose
Oral doses of nystatin in excess of five million units daily have caused nausea and gastrointestinal upset.

5.Pharmacological Properties

5.1 Pharmacodynamic Properties
Pharmacotherapeutic group: Antifungal
ATC code: A07AA02
Nystatin relates to polyene antibiotic group. It's structure has molecules with big quantities of double bonds, stipulating for high tropicity of agent to stearic formations of thyroplasma membrane of fungi. As a result molecule is embedded into the cell membrane with formation of a quantity of cannels promoting to uncontrolled transport of water, electrolytes and nonelectrolytes. The cell losses resistance to attacks of outside osmotic forces and is lysed.
Nystatin is active to yeast-like fungus of Candida and Aspergillus generation.
Tolerance progress to nystatin of sensitive fungus is very slow.

5.2 Pharmacokinetic Properties
The preparation is poorly absorbed in gastrointestinal tract. The main quantity of intaken drug is fecal exctreted, during the period of lactation small quantities are secreted with breast milk. Nystatin has no accumulated properties.

5.3 Pre Clinical Safety Data
There are no preclinical data of relevance.

6.Pharmaceutical Particulars
6.1 List of Excipients

Maize starch
Dibasic Calcium Phosphate
Microcrystalline cellulose
Croscarmellose Sodium
Aerosil
Gelatin
Tween 80
Maize Starch (paste)
Sodium Methyl Paraben
Sodium Propyl Paraben
PVPK 30
Purified Water BP
Talcum
Magnesium Stearate
Aerosil
Sodium Starch Glycolate
Titanium Dioxide
Talcum
PEG 6000
HPMC
Iso propyl alcohol
Methylene dichloride

6.2 Incompatibilities

Not applicable

6.3 Shelf Life
3 years

6.4 Special precautions for Storage
Do not store above 25 °C. Store in the original package.

6.5 Nature and contents of Container
10 tablets packed in an Alu/Pvc blisters , such 10 Blisters are packed in an mono carton along with insert.

6.6 Special precautions for disposal
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. REGISTRANT

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8. MANUFACTURER

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9. DATE OF REVISION OF THE TEXT

Applicable once the registration is obtained.