1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1. Name of the medicinal product

Nystatin tablets USP 500,000 IU

2. Qualitative and quantitative composition

Composition:

Each tablet contains:

Nystatin USP ……. 500000 IU

S. no	Name of Ingredients	Function of ingredients	Quantity required per tab in mg	Overage (%)	Quantity required per tablet	Water/LOD content (%)	Total quantity required per tablet
Active							
1.	Nystatin USP	Active ingredient	77.507 mg.	3%	79.83 mg.	Nil	79.83 mg.
Inactive							
2.	Corn Starch USP	Diluent	117.193 mg.	Nil	117.193 mg.	Nil	117.193 mg.
3.	Lactose monohydrate USP	Diluent	112.700 mg	Nil	112.700 mg	Nil	112.700 mg.
4.	Corn Starch USP	Binder	17.5 mg	Nil	17.5 mg	Nil	17.5 mg.
5.	Methylparaben sodium USP	Preservative	1.0 mg	Nil	1.0 mg	Nil	1.0 mg.
6.	Propyl paraben sodium USP	Preservative	0.1 mg	Nil	0.1 mg	Nil	0.1 mg.
7.	PovidoneUSP	Disintegrant	10.0 mg	Nil	10.0 mg	Nil	10.0 mg.
8.	Purified water USP	Solvent	70.0 mcl	Nil	70.0 mcl	Nil	70.0 mcl
9.	Colloidal Silicon Dioxide USP	Glidant	1.750 mg	Nil	1.750 mg	Nil	1.750 mg.
10.	Magnesium Stearate USP	Lubricant	7.000 mg	Nil	7.000 mg	Nil	7.000 mg.
11.	Talc USP	Glidant	5.250 mg	Nil	5.250 mg	Nil	5.250 mg.
Avg. weight of tablet before film coating: 350 mg							

FILM COATING INGREDIENTS:

Name of Ingredients	Quantity (per tablet)	Total quantity required
Methylene chloride USP	91.000 mg	91.000 mg
Isopropyl Alcohol USP	49.000 mg	49.000 mg
Polyethylene Glycol USP	1.400 mg.	1.400 mg.
Hypromellose USP	5.250 mg	5.250 mg
Methylparaben USP	0.035 mg	0.035 mg
Propylparaben USP	3.500 mcg	3.500 mcg
Colour Titanium Dioxide USP	0.210 mg.	0.210 mg.
Talc USP	0.700 mg.	0.700 mg.
Colour Iron Oxide Red Lake	0.840 mg.	0.840 mg.
Colour Ponceau 4R Lake	0.980 mg	0.980 mg
Avg. weight of tablet Before film coating: 350 mg **Avg. weight of tablet After film coating : 357 mg**		

3. Pharmaceutical form

Film Coated Tablet

4. Clinical particulars

4.1 Therapeutic indications

Indications

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

The Tablet also provides effective prophylaxis against oral candidosis in those born of mothers with vaginal candidosis.

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

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

Tell your doctor and pharmacist if you are allergic to nystatin, any other medications, or any of the ingredients in nystatin tablets or suspension. Ask your pharmacist for a list of the ingredients.

Tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take.

Tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while using nystatin, call your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

At simultaneous using of nistatin with clotrymasol the activity of the latter is lowered.

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 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungals 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

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. Nistatin has no accumulated properties.

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 mutagenicity of nystatin or its effect on male or female fertility.

6. Pharmaceutical particulars

6.1 List of excipients

Corn Starch USP
Lactose monohydrateUSP
Methylparaben sodium USP
Propyl paraben sodium USP
Povidone USP
Purified water USP
Colloidal Silicon DioxideUSP
Magnesium Stearate USP
Talc USP
Methylene chloride USP
Isopropyl Alcohol USP
Polyethylene Glycol USP
Hypromellose USP
Methylparaben USP
Propylparaben USP
Colour Titanium Dioxide USP
Colour Iron Oxide Red Lake
Colour Ponceau 4R Lake

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months.

6.4 Special precautions for storage

Store below 30ºC. Protect from light.

6.5 Nature and contents of container

Brown colored, round shaped, biconvex, film coated tablet having both sides plain packed in blister strip.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

1.3.2 Labeling (outer & inner labels)

== Enclosed ==