SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT:

1.1	Brand Name	:	**Nystaleb Oral Suspension**
1.2	Generic Name	:	Nystatin Oral Suspension BP
1.3	Strength	:	Nystatin BP 1,00,000 IU /ml
1.4	Pharmaceutical Form	:	Suspension

2. QUALITATIVE & QUANTITATIVE COMPOSITION:

Each ml. contains:

Nystatin	BP	1,00,000 IU
Flavoured base		q.s.

3. PHARMACEUTICAL FORM

Suspension

Yellow coloured, flavoured, palatable Suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Nystatin Oral Suspension is indicated for the treatment of intestinal candidiasis, oropharyngeal Candidiasis.

4.2 Posology and method of administration

- **For the treatment of intestinal candidiasis:**

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

- **For the treatment of oropharyngeal candidiasis (thrush):**

  Adults, Adolescents, and Children: 400,000 to 600,000 units (4 to 6 mL) orally swished in the mouth four times daily; each dose is divided so that one-half of each dose is placed on each side of the mouth. Continue treatment for at least 48 hours after symptoms are resolved.

  Neonates and Infants: 200,000 units (2mL) orally four times daily; each dose is divided so that one-half of each dose is placed on each side of the mouth. Avoid feeding for 5 to 10 minutes. Continue treatment for at least 48 hours after symptoms are resolved.

  Premature Neonates: 100,000 units (1mL) orally four times daily based on limited data in premature and low birth weight neonates; each dose is divided so that one-half of each dose is placed on each side of the mouth. Avoid feeding for 5 to 10 minutes. Continue treatment for at least 48 hours after symptoms are resolved.

  SHAKE WELL BEFORE USE.

4.3 Contraindications

Nystaleb (Nystatin) is contraindicated in those patients with a history of hypersensitivity to any of the components.

4.4 Special warnings and special precautions for use

This medication is not to be used for the treatment of systemic mycoses.

4.5 Interaction with other FPPs and Other forms of Interaction

The combination of econazole, Ketoconazole, Miconazole, Oxiconazole, Sertaconazole, Sulconazole with nystatin represents a duplication of therapy whenever the drugs are used by similar routes and are usually avoided.

4.6 Pregnancy and lactation

It is not known whether nystatin can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. 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 breastfeeding woman.

4.7 Effects on ability to drive and use machines

Not Known

4.8 Undesirable effects

Nystatin is generally well tolerated by all age groups, even during prolonged use. If irritation or sensitization develops, treatment should be discontinued. Nausea has been reported occasionally during therapy. Large oral doses of nystatin have occasionally produced diarrhea, gastrointestinal distress, nausea, and vomiting. Rash, including urticaria, has been reported rarely. Hypersensitivity and angioedema, including facial oedema, have been reported.

4.9 Overdose & Treatment

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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungal

Mechanism of action:

Nystatin binds to ergosterol, a major component of the fungal cell membrane. When present in sufficient concentrations, it forms pores in the membrane that lead to K+ leakage, acidification, and death of the fungus. However, many of the systemic/toxic effects of nystatin in humans are attributable to its binding to mammalian sterols, namely cholesterol. This is the effect that accounts for the nephrotoxicity observed when high serum levels of nystatin are achieved.

Microbiology: Nystatin is both fungistatic and fungicidal in vitro against a wide variety of yeasts and yeast-like fungi. Candida albicans demonstrate no significant resistance to nystatin in vitro on repeated subculture in increasing levels of nystatin; other Candida species become quite resistant. Generally, resistance does not develop in vivo. Nystatin exhibits no appreciable activity against bacteria, protozoa, or viruses.

5.2 Pharmacokinetic properties

Gastrointestinal absorption of nystatin is insignificant. Most orally administered nystatin is passed unchanged in the stool. In patients with renal insufficiency receiving oral therapy with conventional dosage forms, significant plasma concentrations of nystatin may occasionally occur.

5.3 Preclinical safety data

None Known

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

SN	Ingredients	Spec.
1.	Sucrose	BP
2.	Glycerin	BP
3.	Sod. Methyl Hydroxybenzoate	BP
4.	Sod. Propyl Hydroxybenzoate	BP
5.	Carmellose Sodium (C. M. C. Sodium (KDA8400))	BP
6.	Saccharin Sodium	BP
7.	Essence Mixed Fruit Flavour (S1038)	IH
8.	Purified Water	BP

6.2 Incompatibilities

Not Known

6.3 Shelf life

24 months

6.4 Special precautions for storage

Do not Freeze. Protect from light. Keep out of reach of children. Keep container tightly closed. Store at a temperature not exceeding 30°C.

6.5 Nature and contents of container

30 ml. in an amber-colored PET bottle with 1 ml. dropper in an inner carton.

6.6 Instructions for use and handling

Please see the package insert.

7. MARKETING AUTHORISATION HOLDER AND MANUFACTURING SITE ADDRESS

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8. MARKETING AUTHORISATION NUMBER

AMD/12/2002 & AMD/6/2002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

a) Date of first authorization: 21/01/1989.

b) Date of latest renewal: 01/01/2018.

10. DATE OF REVISION OF THE TEXT

01/01/2023