The format of this leaflet was determined by the Ministry of Health and its content was checked and approved in March 2016

Nystatin Ready Mix
Oral Suspension

Summary of Product Characteristics

1. Name of the medicinal product
Nystatin Ready Mix

2. Qualitative and quantitative composition
Nystatin Ready Mix containing 100,000 units nystatin per ml.
For the full list of excipients, see section 6.1.

3. Pharmaceutical form
Oral suspension

4. Clinical particulars
4.1 Therapeutic indications
For the treatment of oral fungal infections.

4.2 Posology and method of administration
Neonates (from birth to 1 month):
Clinical studies of limited size in neonates, including preterm and babies of low weight at birth, indicate that 1 ml (100,000 U) four times daily is an effective regimen.

Infants (1 month to 5 years):
2 ml (200,000 U) 4 times daily (1 ml for each side of the mouth).

Children (over 5 years) and adults:
4 – 6 ml (400,000 – 600,000 U) 4 times daily (half dose in each side of the mouth). It is recommended to keep the medication in contact with the affected areas as long as possible.

Older people:
No specific dosage recommendations or precautions.

The preparation should be retained in the mouth as long as possible before swallowing. The longer the suspension is kept in contact with the affected area in the mouth, before swallowing, the greater will be its effect.

In the prevention and treatment of candidiasis, the dosage regimen for Nystatin should be continued for at least 48 hours after symptoms have disappeared. If signs and symptoms worsen or persist (beyond 14 days of treatment), the patient should be reevaluated, and alternate therapy considered.

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
Nystatin Ready Mix contains sucrose and sodium.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltaseinsufficiency should not take this medicine.
This medicinal product contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).
Nystatin oral preparations should not be used for treatment of systemic mycoses.

4.5 Interaction with other medicinal products and other forms of interaction
None known.

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 absorptionof nystatin from the gastro-intestinal tract is negligible. Nystatin should be prescribed during pregnancy only if thepotential benefits to be derived outweigh the potential risk to the foetus.

Breast-feeding:
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 nursing woman.

4.7 Effects on ability to drive and use machines
None known.

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 suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:
(http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il).

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 an antifungal antibiotic active against a wide range of yeasts and yeast-like fungi, including *Candida albicans*.

5.2 Pharmacokinetic properties
Absorption
Nystatin is formulated in oral and topical dosage forms and is not systemically absorbed from any of thesepreparations.

Gastrointestinal absorption of nystatin is insignificant.

Elimination
Most orally administered nystatin is passed unchanged in the stool.

5.3 Preclinical safety data
No long-term animal studies have been performed to evaluate the carcinogenic potential of nystatin. No studies havebeen performed to determine the mutagenicity of nystatin or its effect on male or female fertility.

6. Pharmaceutical particulars
6.1 List of excipients
Sucrose, sorbitol solution70%, propylene glycol, aluminium hydroxide gel, methyl paraben, cinnamaldehyde, anethole, sodium saccharine, propyl paraben, purified water.

1 ml of Nystatin Ready Mix contains:
500 mg of sucrose
0.06 mg of sodium

6.2 Incompatibilities
None known.

6.3 Shelf life
12 months.

6.4 Special precautions for storage
Do not store above 25°C.

6.5 Nature and contents of container
Yellow suspension in a 30 ml glass bottle, with a pipette.

6.6 Special precautions for disposal and other handling
Shake well before use.
Dilution is not recommended as this may reduce therapeutic efficacy.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. Marketing authorisation holder

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8. Marketing authorisation number(s)
12350.25007