1. NAME OF THE MEDICINAL PRODUCT

Nystimex, 100 000 IU/ml oral suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains 100 000 IU nystatin.

Excipients: Methyl parahydroxybenzoate 1 mg
Sodium 1.2 mg/ml, equivalent to 0.041 mmol/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension

Light yellow, opalescent suspension with peppermint odour and flavour

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Oral and intestinal candidiasis. As adjuvant treatment with other local nystatin preparations to prevent reinfection.

4.2 Posology and method of administration

Oral candidiasis:

Posology
Adults, children and infants: 1 ml (100,000 IU) 4 times daily. The dose may be increased if necessary.

Duration of treatment
Usual treatment duration for oral candidiasis is 1-2 weeks.
Treatment may be prolonged to 4 to 6 weeks in special circumstances, such as in immunocompromised patients.

Method of administration
The suspension is preferably taken after meals and is retained in the mouth for as long as possible before swallowing. For infants, the suspension may be administered drop by drop or diluted with water and brushed on the lesions.
The bottle should be shaken well before use

Intestinal candidiasis

Posology
Adults: 5 ml (500,000 IU) 3 times daily. The dose may be doubled if necessary.
Children and infants: 1 ml (100,000 IU) 4 times daily.
Duration of treatment.

Treatment should continue for 2-3 days after symptoms have ceased, in order to prevent relapse. When used in combination with antibiotics, nystatin treatment should be given at least as long as the antibiotic in question.

Method of administration
The suspension is swallowed directly.
The bottle should be shaken well before use.

If skin or mucosal lesions are present, treatment with Nystatin cream or ointment should occur simultaneously.

4.3 Contraindications

Hypersensitivity to the active substance (nystatin) or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Nystatin oral suspension should not be used for the treatment of systemic mycoses.
If irritation or hypersensitivity reactions occur, treatment should be discontinued.

Nystimex contains methyl parahydroxybenzoate. May cause allergic reactions (possibly delayed).

Nystimex is essentially sodium free.

4.5 Interaction with other medicinal products and other forms of interaction

No known.

4.6 Fertility, pregnancy and lactation

Pregnancy
It is not known whether nystatin can cause fetal harm when administered to a pregnant woman. Animal studies have shown reproductive toxicity (see section 5.3). Nystatin should only be prescribed to a pregnant woman if the potential benefit to the mother justifies the potential risk to the fetus.

Breastfeeding
It is not known whether nystatin is excreted in human milk. Although the gastrointestinal absorption is negligible, caution should be exercised when nystatin is prescribed to a nursing woman.

Fertility
No clinical data are available concerning the effect of nystatin on fertility. A study in rats did not show any negative effects on fertility (see section 5.3).

4.7 Effects on ability to drive and use machines

Nystatin is assumed not to affect the ability to drive or operate machinery.

4.8 Undesirable effects

Adverse reactions are listed by system organ class and absolute frequency. Frequencies are defined as Very Common (≥1/10), Common (≥1/100, <1/10), Uncommon (≥1/1000, <1/100), Rare (≥1/10,000 to <1/1000) or Very rare (<1/10,000), no known frequency (can not be estimated from available data).

Immune system:	Very rare, no known frequency	Hypersensitivity and

		Angioedema, including swelling of the face, have been reported.
Gastrointestinal	Uncommon	Nausea, vomiting, dyspepsia and diarrhea.
Skin and subcutaneous tissue	Uncommon	Rash and urticaria
	Rare	Stevens Johnson Syndrome

Nausea and diarrhoea is dose related.

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. Healthcare professionals are asked to report any suspected adverse reactions via the national reporting system.
<***To be completed nationally***>

4.9 Overdose

Doses 4-8 times more than recommended per day have given nausea and gastrointestinal problems such as vomiting and diarrhea. Treatment: gastric emptying, if necessary, active carbon. Symptomatic treatment.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: antibiotic antifungal, ATC code: A07AA02

Nystatin is obtained from *Streptomyces noursei* and is constituted of a yellow powder, almost insoluble in water. Nystatin is fungistatic or fungicidal depending on the concentration achieved and the susceptibility of the fungus. Nystatin has an effect on several species of fungi, but not on bacteria, protozoa nor viruses, and does not affect the body's normal bacterial flora. Most sensitive is the yeast-like fungi and the effect on *Candida albicans* is specific.
A modified membrane permeability is achieved by binding to sterols in the fungal cell wall, resulting in leakage of cell contents. It is well tolerated, even during long-term treatment, and development of resistance by nystatin has not been observed. Nystatin prevents gastrointestinal super infections of Candida in antibiotic therapy.

5.2 Pharmacokinetic properties

Nystatin is absorbed to a small extent from the gastrointestinal tract and is excreted largely unchanged in the faeces.

5.3 Preclinical safety data

No studies have been made to evaluate mutagenic or carcinogenic effect of nystatin.
Fertility and developmental toxicity studies (segment I, II and III) were carried out with nystatin in rats and rabbits. Parental mortality and toxicity at the higher dose (3.0 mg/kg/day) was observed in all studies. Nystatin did not show any effect on the incidence of foetal malformations in rabbits. Despite the parentally toxic doses, nystatin showed no effect on F0 male or female fertility or early embryonic development of F1 offspring in rats. In F1 rats, post-wean development toxicity was observed at all dosage levels. Owing to these toxic effects on postnatal development in F1 rats, caution should be exercised when using nystatin in females of childbearing potential.

Environmental Risk Assessment (ERA)
Nystatin is potentially persistent in the environment and environmental risk is not excluded.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xylitol
Carmellosesodium
Methyl parahydroxybenzoate (E218)
Peppermint oil
Purified water

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Unopened bottle: 2 years
Opened bottle: 1 month

6.4 Special precautions for storage

Unopened bottle store in a refrigerator (2° C - 8° C)
Opened bottle store below 25° C

6.5 Nature and contents of container

Amber glass bottle, 100 ml with aluminium cap
In certain markets a 5 ml graded polyethylene/polystyrene syringe may be provided

6.6 Special precautions for disposal and other handling

No special requirements.

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

7. MARKETING AUTHORISATION HOLDER

RPH Pharmaceuticals AB
Box 603
101 32 Stockholm
Sweden

8. MARKETING AUTHORISATION NUMBER(S)

<[To be completed nationally]>

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

<Date of first authorisation: {DD month YYYY}>
<Date of latest renewal: {DD month YYYY}>

<[To be completed nationally]>

10. DATE OF REVISION OF THE TEXT

2025-07-10
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