SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nystan 100,000 units/ml Oral Suspension (Ready-Mixed)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Ready mixed oral suspension containing 100,000 units nystatin per ml.

Excipient(s) with known effect:
Excipients with known effect: ethanol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), sodium and sucrose.
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

The prevention and treatment of candidal infections of the oral cavity, oesophagus and intestinal tract. The suspension provides effective prophylaxis against oral candidosis in those born of mothers with vaginal candidosis.

4.2 Posology and method of administration

Posology

Adults:

For the treatment of denture sores, and oral infections in adults caused by C.albicans, 1 ml of the suspension should be dropped into the mouth four times daily; it should be kept in contact with the affected areas as long as possible.

Children:
In intestinal and oral candidosis (thrush) in infants and children, 1 ml should be dropped into the mouth four times a day. The longer the suspension is kept in contact with the affected area in the mouth, before swallowing, the greater will be its effect.

For prophylaxis in the newborn the suggested dose is 1 ml once daily.

Older people:
No specific dosage recommendations or precautions.

In the prevention and treatment of candidiasis, the dosage regimen for Nystan 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

Nystan Oral Suspension contains sucrose.
Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains 228 mg of alcohol (ethanol) in each 30 ml which is equivalent to 0.76 g in 100 ml. The amount in 1 ml of this medicine is equivalent to less than 0.2 ml of beer or 0.1 ml of wine.
The small amount of alcohol in this medicine will not have any noticeable effects.

This medicinal product contains methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possibly delayed).

This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially “sodium free”.

Nystan 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 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 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 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 Yellow Card Scheme at:
www.mhra.gov.uk/yellowcard

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: Intestinal Antiinfectives, ATC code: A07AA02
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 these preparations.
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 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

Ethanol, flavours*, glycerin, methyl parahydroxybenzoate (E218), pH adjusters (hydrochloric acid, sodium hydroxide), propyl parahydroxybenzoate (E216), sodium carboxymethylcellulose (E466), sodium phosphate, sucrose, water.
*Cherry flavour, cinnamic aldehyde, peppermint oil.

6.2 Incompatibilities

None known.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Bottle filled with 30 ml, packed in a cardboard carton with a graduated (in 0,5 ml steps) syringe and an adapter.

6.6 Special precautions for disposal

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

Vygoris Limited
930 High Road
London
N12 9RT
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 47587/0005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28/11/1990

10 DATE OF REVISION OF THE TEXT

25/07/2023