NEW ZEALAND DATA SHEET

1. NAME OF THE MEDICINAL PRODUCT

NYSTATIN DEVATIS 100,000 IU/mL Oral Drops

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Drug Substance:
Ready mixed oral suspension containing 100,000 IU nystatin per mL.

Excipient(s) with known effect:
Ethanol, Methyl parahydroxybenzoate, Propyl parahydroxybenzoate, sodium and sucrose.
For the full list of excipients see 6.1.

3. PHARMACEUTICAL FORM

Oral drops.
Light creamy, yellow, homogenous, cherry-peppermint flavored easily re-suspendable, particle-free opaque suspension.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications
The treatment of infections of the oral cavity caused by *Candida albicans*.

4.2 Posology and method of administration

Posology
Infants, children and adults:- 1 mL (100,000 units) 4 times daily.

Method of administration
The dose should be administered under the tongue or in the buccal cavity and swirled around the mouth for as long as possible before swallowing.

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 DEVATIS 100,000 IU/mL Oral Drops should not be used for treatment of systemic mycoses. If irritation or sensitization develops, treatment should be discontinued.

If there is a lack of therapeutic response, appropriate microbiological studies should be repeated to confirm diagnosis of candidiasis and rule out the pathogens before instituting another course of therapy.

Use in immunocompromised patients
Higher doses, for example 500,000 units 4 times daily may be needed. However, the use of alternate antifungal antibiotics is preferred for the treatment of oral thrush in patients with immunosuppression.

This medicinal product contains sucrose. Patients with rare hereditary problems of fructose intolerance, glucose –galactose malabsorption or sucrose -isomaltase insufficiency should not take this medicine.

This medicinal product contains small amounts of ethanol (alcohol), less than 100 mg per dose.

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

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

4.6 Pregnancy and lactation

General Advice: Pregnancy category is A

Pregnancy
Systemic absorption of nystatin is negligible after topical, vaginal, or oral administration. However, as with all medicines, caution should be exercised when nystatin is administered to pregnant women.

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 breast-feeding 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 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. Steven-Johnson Syndrome has been reported very rarely.
Hypersensitivity and angioedema, including facial edema have been reported.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions via: https://nzphvc.otago.ac.nz/reporting.

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.

Symptoms as described in the Undesirable Effects section would be expected. There are no specific guidelines relating to the treatment of overdosage with Nystatin. For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungals for topical use,
ATC code: D01AA01
Nystatin is an antifungal antibiotic, produced by a strain of Streptomyces noursei, active against yeasts and yeast like fungi, including *Candida albicans*. The antifungal activity is probably due to the binding of sterols

in the cell membrane of the fungus with a resultant change in membrane permeability allowing leakage of intracellular components. Nystatin has no appreciable activity against bacteria.

5.2 Pharmacokinetic properties

Absorption
Nystatin is absorbed very sparingly following oral administration when given in the recommended doses. The minimal absorption from oral dosage forms may however, be sufficient to provoke an allergic reaction in hypersensitive patients.

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
Cinnamaldehyde
Imitation Cherry Flavor
Glycerol
Methyl parahydroxybenzoate
Propyl parahydroxybenzoate
Peppermint oil
Sucrose
Carmellose sodium
Disodium phosphate anhydrous
Ethanol 96%
Hydrochloric acid
Purified water

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 months

6.4 Special precautions for storage
Store at or below 25°C. Discard 14 days after opening.

6.5 Nature and contents of container
NYSTATIN DEVATIS 100,000 IU/mL Oral Drops are available in a 60 mL Type III amber glass bottle containing 48 mL suspension, sealed with a with a tamper evident polyethylene cap. Bottles are packed in cardboard box with a graduated, plastic dropper with natural rubber teat.

6.6 Special precautions for disposal and other handling
Any unused material should be disposed according to local disposal regulations.

7. MEDICINE SCHEDULE

Restricted Medicine

8. SPONSOR

DEVATIS LIMITED
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9. DATE OF FIRST APPROVAL

Date of first authorization: 27/05/2021
Date of latest renewal:

10. DATE OF REVISION OF THE TEXT