New Zealand Data Sheet

1. MYCOSTATIN (Topical Cream, 100000 U/mL)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Mycostatin (Nystatin), 100,000 units/g: 15 g.

3. PHARMACEUTICAL FORM

Topical cream 15g.

4. CLINICALT PARTICULARS

4.1 Therapeutic indications

Nystatin topical preparations are indicated in the treatment of cutaneous or mucocutaneous mycotic infections caused by Candida species.
This preparation is not indicated for systemic use.

4.2 Dose and method of administration

Apply liberally to affected areas twice daily or as indicated until healing is complete.

4.3 Contraindications

Known sensitivity to nystatin or other components.

4.4 Special warnings and precautions for use

Should a reaction of hypersensitivity occur, the drug should be immediately withdrawn and appropriate measures taken. Nystatin topical preparations should not be used for the treatment of systemic or ophthalmic infections.
It is recommended that KOH smears, cultures, or other diagnostic methods be used to confirm the diagnosis of cutaneous or mucocutaneous candidiasis and to rule out infection caused by other pathogens.

Information for the Patient

Patients using these medications should receive the following information and instructions:

1. The patient should be instructed to use the medication as directed (including the replacement of missed doses). The medication is not for any disorder other than that for which it was prescribed.
2. Even if symptomatic relief occurs within the first few days of treatment, the patient should be advised not to interrupt or discontinue the medication until the prescribed course of treatment is completed.
3. If symptoms of irritation develop, the patient should be advised to notify the physician promptly.

Laboratory Test

If there is a lack of therapeutic response, KOH smears, cultures or other diagnostic methods should be repeated.

Carcinogenesis and Mutagenesis
No long-term animal studies have been performed to evaluate the carcinogenic potential of nystatin.

4.5 Interaction with other medicines and other forms of interaction

4.6 Fertility, pregnancy and lactation

Fertility
No studies have been performed to
determine the mutagenicity of nystatin or its effect on male or female fertility.

Pregnancy
(Category A)
Animal reproduction studies have not been conducted with nystatin topical preparations. It is also not known whether these preparations can cause foetal
harm when used by a pregnant woman or can affect reproductive capacity. Nystatin topical preparations should be prescribed for a pregnant woman only if the potential benefit to the mother outweighs the potential risk to the foetus.

Lactation
It is not known whether nystatin is excreted in human milk. Caution should be exercised when nystatin is prescribed for a nursing mother.

4.7 Effect of ability to drive and use machinery

No data available.

4.8 Undesirable effects

Well tolerated by all age groups including debilitated infants, even on prolonged administration. Local irritation and sensitisation (including: rash, dermatitis, pruritus and burning) have been reported. If irritation on topical application should occur, discontinue medication.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation 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 https://nzphvc.otago.ac.nz/reporting/

4.9 Overdose

No data available.

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

Actions

Nystatin is a polyene antifungal antibiotic obtained from Streptomyces noursei.

Microbiology

Nystatin is an antibiotic which is both fungistatic and fungicidal in vitro against a wide variety of yeasts and yeast-like fungi. Nystatin acts by binding to sterols in the cell membrane of susceptible Candida species resulting in a change in membrane permeability and the subsequent leakage of intracellular components.

On repeated subculturing with increasing levels of nystatin, Candida albicans does not develop resistance to nystatin. Generally, resistance to nystatin does not develop during therapy. Nystatin exhibits no activity against bacteria,protozoa or viruses.

5.2 Pharmacokinetic properties

Nystatin is not absorbed from intact skin or mucous membranes.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium hydroxide gel, perfume, promulgen D, propylene glycol, purified water, simeticone, sorbitol, titanium dioxide, water, white soft paraffin.

6.2 Incompatibilities

No data available.

6.3 Shelf-life

24 months from date of manufacture.

6.4 Special precautions for storage

Store at or below 25°C

6.5 Nature and contents of container

1 x 15 g tube (100,000 units/g)

6.6 Special precautions for disposal

No data available.

7. MEDICINE SCHEDULE

Pharmacy only

8. SPONSORS

Pharmacy Retailing (NZ) Ltd t/a Healthcare Logistics
58 Richard Pearse Drive
Airport Oaks

Mangere
AUCKLAND

9. DATE OF FIRST APPROVAL

18 November 2009

10. DATE OF REVISION OF THE TEXT

May 2019

SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
All sections revised	Update to the SPC-style format