Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nystaform 100,000 U/g, 1.0% w/v Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The product contains Nystatin 100,000 U/g and Chlorhexidine acetate 1.0% w/w in a water-repellent base.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment.
A yellow ointment for topical application.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Nystaform Ointment is indicated for the treatment of infected skin conditions where fungal (particularly candidal) and/or bacterial infections are present.

4.2 Posology and method of adminstration

Adults and children:

For topical application only. Apply to the infected areas two to three times daily. Continue application for one week after lesions have healed.

The patient should be advised that if the condition has not improved within seven days, to return to their doctor for further consultation. If the condition does not improve within 14 days of starting treatment, an alternative treatment should be substituted.

4.3 Contraindications

Hypersensitivity to the active substance or to the excipient.

Do not use in the eye.

4.4 Special warnings and precautions for use

For external use only. If sensitivity occurs, or if new infection appears, discontinue use and institute alternative therapy.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

Do not use in pregnancy and lactation unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

Side-effects are uncommon. Hypersensitivity-type reactions including application site reaction and allergic reactions have been reported rarely.

4.9 Overdose

Accidental oral ingestion

Nystatin is poorly absorbed from the gastro-intestinal tract. If ingested, routine measures such as gastric lavage should be performed as soon as possible.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Topical antifungal antibiotics, ATC code: D01AA20.

Nystatin is a fungistatic and fungicidal antibiotic primarily effective against *Candida albicans*. Chlorhexidine is active against a wide range of bacteria.

5.2 Pharmacokinetic properties

Nystatin is poorly absorbed from the gastro-intestinal tract and is NOT absorbed through the skin or mucous membranes when applied topically.

5.3 Preclinical safety data

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin.

6.2 Incompatibilities

Not applicable.

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

30g resin-lined aluminium tubes with polyethylene caps contained in an outer cardboard carton.
Only one pack size.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 219/3/2

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10 DATE OF REVISION OF THE TEXT

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