Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nystaform HC 100,000 U/g 1.0% w/w, 0.5% w/w Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The product contains Nystatin 100,000 U/g, Chlorhexidine hydrochloride 1.0% w/w and Hydrocortisone 0.5% w/w in a water-miscible base.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream
A light yellow cream for topical application.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Nystaform HC Cream is indicated for the treatment of infected dermatoses 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. Treatment should be for a maximum period of seven days.

4.3 Contraindications

The presence of infections of viral, treponemal or tuberculous origin, or those due to non-susceptible organisms. Hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

For external use only. Avoid contact with eyes. If sensitivity occurs, or if new infection appears, discontinue use and institute alternative therapy. Cetostearyl alcohol may cause local skin reaction (e.g. contact dermatitis).

Continuous treatment for longer than seven days should be avoided in patients under the age of three years. Adrenal suppression can occur even without occlusion. As with other topical corticosteroids, systemic absorption may occur when extensive areas are treated, particularly under occlusion. Prolonged local application may induce dermal atrophy and formation of striae.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Pregnancy and lactation

This product should not be used 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. Hydrocortisone exercises a vasoconstrictive effect, thus reducing inflammation and oedema, and also has an antipruritic effect.

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. Hydrocortisone is absorbed through the skin and is metabolised by the liver and most body tissues to hydrogenated and degraded forms such as tetrahydrocortisone and tetrahydrocortisol. These are excreted in the urine, mainly conjugated as glucuronides, together with a very small proportion of unchanged hydrocortisone.

5.3 Preclinical safety data

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intrauterine growth retardation. The relevance of this finding to humans has not been established.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl Alcohol
Octyldodecanol
Polysorbate 60
Sorbitan stearate
Cetyl Esters Wax
Benzyl Alcohol
Purified Water

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

15g and 30g resin-lined aluminium tubes with polyethylene caps contained in an outer cardboard carton.
Not all pack sizes may be marketed.

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 219/4/1

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Date of last renewal: 8 May 2005.

10 DATE OF REVISION OF THE TEXT

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