SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Nystaform HC Cream
Nystatin/Chlorhexidine hydrochloride/Hydrocortisone 100,000 units/g /1% /0.5% Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The product contains nystatin 100,000 I.U./g, chlorhexidine hydrochloride 1.0% w/w and hydrocortisone 0.5% w/w in a water-miscible base.

Excipient(s) with known effect:
Cetostearyl alcohol 100 mg per gram of cream
Benzyl alcohol 10 mg per gram of cream

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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 monilial) and/or bacterial infections are present.

4.2 Posology and method of administration

Posology

Adults and Children:

Apply to infected areas 2-3 times daily.

Treatment should be for a maximum period 7 days.

Method of administration

For topical application only.

4.3 Contraindications

Tuberculous lesions of the skin. Known hypersensitivity to the active substances, especially in those with a history of possible chlorhexidine-related allergic reactions (see sections 4.4 and 4.8), or to any of the excipients listed in section 6.1.

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 reactions (e.g. contact dermatitis).

This medicine contains 10 mg benzyl alcohol in each gram of cream. Benzyl alcohol may cause allergic reactions and mild local irritation.

Long term use of topical steroids can result in the development of rebound flares after stopping treatment (topical steroid withdrawal syndrome). A severe form of rebound flare can develop which takes the form of a dermatitis with intense redness, stinging and burning that can spread beyond the initial treatment area. It is more likely to occur when delicate skin sites such as the face and flexures are treated. Should there be a reoccurrence of the condition within days to weeks after successful treatment a withdrawal reaction should be suspected. Reapplication should be with caution and specialist advise is recommended in these cases or other treatment options should be considered.

The label will state mild steroid.

Paediatric population

In infants, long-term continuous topical steriod therapy should be avoided. Adrenal suppression can occur even without occlusion. As with other topical corticosteroids, systemic absorption may occur when extensive areas are treated, particularly under occlusion.

Nystaform HC Cream contains chlorhexidine. Chlorhexidine is known to induce hypersensitivity, including generalised allergic reactions and anaphylactic shock. The prevalence of chlorhexidine hypersensitivity is not known, but available literature suggests this is likely to be very rare. Nystaform HC Cream should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound (see sections 4.3 and 4.8).

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, pregnancy and lactation

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. The relevance of this finding to humans has not been established. However, topical steroids should not be used extensively in the first trimester of pregnancy and nystatin only with caution. The use of Nystaform HC Cream requires that the anticipated benefits outweigh the possible risks.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

The following local adverse reactions are reported infrequently with topical corticosteroids but may occur more frequently with the use of occlusive dressings. These reactions are listed in an approximate decreasing order of occurrence; burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneform eruptions, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, miliaria, striae and thinning and dilations of superficial blood vessels producing telangiectasia.

Prolonged use of large doses to extensive areas can result in sufficient systemic absorption to produce generalised manifestations of steroid toxicity and may result in depression of HPA function on discontinuing treatment.

Manifestations of Cushing's Syndrome, hyperglycaemia and glycosuria have occurred in some patients.

Manifestations of adrenal suppression in children include linear growth retardation, delayed weight gain, low plasma cortisol levels and absence of response to ACTH stimulation. Intracranial hypertension including bulging fontanelles, headaches and bilateral papilloedema have also been reported in children receiving topical corticosteroids.

Infected skin lesions, viral, bacterial or fungal may be substantially exacerbated by topical steroid therapy. Wound healing is significantly retarded.

Hypersensitivity reactions may occur.

Skin and Subcutaneous Tissue Disorders Not known (cannot be estimated from available data) Withdrawal reactions - redness of the skin which may extend to areas beyond the initial affected area, burning or stinging sensation, itch, skin peeling, oozing pustules. (see section 4.4)

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 or search for MHRA Yellow Card Scheme in the Google Play or Apple App Store.

4.9 Overdose

Nystatin is poorly absorbed from the gastro-intestinal tract. In the event of accidental oral ingestion, routine measures such as gastric lavage should be performed as soon as possible after ingestion.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antibiotics in combination with corticosteroids, ATC code: D01AA20.

Nystatin is a fungistatic and fungicidal medicine primarily effective against *Candida albicans.* Chlorhexidine has activity against a wide range of bacteria. Hydrocortisone is a mildly potent corticosteroid and 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

None stated.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Cetostearyl alcohol	Ph.Eur
Octyldodecanol	Ph.Eur
Polysorbate 60	Ph.Eur
Sorbitan stearate	Ph.Eur
Cetyl esters wax	Ph.Eur
Benzyl alcohol	Ph.Eur
Purified water	Ph.Eur

6.2 Incompatibilities

None stated.

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.

6.6 Special precautions for disposal

For external use only. Avoid contact with eyes.

7 MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

PL 00551/0019

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/05/2005

10 DATE OF REVISION OF THE TEXT

13/02/2024