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

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).

Paediatric population

In infants, long-term continuous topical steroid 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

Skin disorders
Frequency not known: Allergic skin reactions such as dermatitis, pruritus, erythema, eczema, rash, urticaria, skin irritation, and blisters.

Immune disorders
Frequency not known: Hypersensitivity including anaphylactic shock (see sections 4.3 and 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.

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

Nystatin is a fungistatic and fungicidal antibiotic primarily effective against *Candida albicans.* Chlorhexidine has activity 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

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

3 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

Typharm Limited
14D Wendover Road
Rackheath Industrial Estate
Norwich
NR13 6LH

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

27/01/2016