# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

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

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The product contains nystatin 100,000 I.U./g, chlorhexidine hydrochloride 1.0% 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 in a water-miscible base for topical application.

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Nystaform cream is indicated for the treatment of infected skin conditions 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. Continue application for 1 week after lesions have healed.

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

Method of administration

For topical application only.

## 4.3 Contraindications

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).

Nystaform 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 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

As with all drugs, nystatin should be administered with caution during the early months of pregnancy and its use 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.

### 5.2 Pharmacokinetic properties

Nystatin is poorly absorbed from the gastro-intestinal tract. It 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

| | |
|---|---|
| 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 25ºC.

### 6.5 Nature and contents of container

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

### 6.6 Special precautions for disposal and other handling

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 00551/0018

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/05/2005

## 10 DATE OF REVISION OF THE TEXT

27/01/2016