

**1. Name of the medicinal product**

NYSTATIN CREAM USP 100000 UNITS

**2. Qualitative and quantitative composition**

SR. NO.	NAME OF THE INGREDIENTS	PHARMACOPEIAL SPECIFICATION	LABLE CLAIM	OVERAGES %	QTY. / 15 GM	PURPOSE
<b>ACTIVE INGREDIENTS</b>						
1.	Nystatin	USP	1,00,000 UNITS	0.00 %	0.300 gm	API
<b>INACTIVE INGREDIENTS</b>						
2.	White soft paraffin	BP	-	0.00 %	1.500 ml	Emulsifier
3.	Light liquid paraffin	BP	-	0.00 %	1.200 gm	Emulsifier
4.	Cetostearyl alcohol	BP	-	0.00 %	0.900 gm	Emulsifier
5.	Cetomacrogol 1000	BP	-	0.00 %	0.975 gm	Emulsifier
6.	Stearic acid	BP	-	0.00 %	0.900 gm	Thickener
7.	Sodium methyl Paraben	BP	-	0.00 %	0.030 gm	Preservative
8.	Sodium propyl Paraben	BP	-	0.00 %	0.015 gm	Preservative
9.	Demineral water	INHOUSE	-	0.00 %	8.880 ml	Vehicle
10.	Propylene glycol	BP	-	0.00 %	0.300 gm	Solvent

**3. Pharmaceutical form**

Topical Cream

**4. Clinical particulars****4.1 Therapeutic indications**

Nystatin 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:**

Rub cream gently into the skin of the affected area.

### 4.3 Contraindications

Known hypersensitivity to the active substance, especially in those with a history of possible chlorhexidine related allergic reactions, 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 reactions (e.g. contact dermatitis).
- Nystatin 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.
- Nystatin Cream should not be administered to anyone with a potential history of an allergic reaction to a chlorhexidine-containing compound.

### 4.5 Interaction with other medicinal products and other forms of interaction

- **Econazole:** Moderate: The combination of econazole and nystatin represents duplication of therapy whenever the drugs are used by similar routes and are usually avoided.
- **Ketoconazole:** Moderate: The combination of ketoconazole and nystatin represents duplication of therapy whenever the drugs are used by similar routes and are usually avoided.
- **Miconazole:** Moderate: The combination of miconazole and nystatin represents duplication of therapy whenever the drugs are used by similar routes and are usually avoided.
- **Miconazole; Petrolatum; Zinc Oxide:** Moderate: The combination of miconazole and nystatin represents duplication of therapy whenever the drugs are used by similar routes and are usually avoided.
- **Oxiconazole:** Moderate: The combination of oxiconazole and nystatin represents duplication of therapy whenever the drugs are used by similar routes and are usually avoided.
- **Sertaconazole:** Moderate: The combination of sertaconazole and nystatin represent duplication of therapy whenever the drugs are used by similar route and are usually avoided.
- **Sulconazole:** Moderate: The combination of sulconazole and nystatin represents duplication of therapy whenever the drugs are used by similar routes and are usually avoided.

### 4.6 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.

#### **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**

- White soft paraffin
- Light liquid paraffin
- Cetostearyl alcohol
- Cetomacrogol 1000
- Stearic acid
- Sodium methyl
- Paraben

- Sodium propyl
- Paraben
- Demineral water
- Propylene glycol

**6.2 Incompatibilities**

None known.

**6.3 Shelf life**

36 months

**6.4 Special precautions for storage**

Store in a dry place at a temperature below 30°C.

**6.5 Nature and contents of container**

15 gm Printed Lami Tube, packed in Printed and Laminated Carton.

**6.6 Special precautions for disposal and other handling**

Not applicable.

**7. Marketing authorisation holder**

West Coast Pharmaceutical Works Ltd, Ahmedabad

**8. Marketing authorisation number(s)**

Not applicable.

**9. Date of first authorisation/renewal of the authorisation**

Not applicable.

**10. Date of revision of the text**

May, 2017