

PACKAGE LEAFLET: INFORMATION FOR THE USER

Nystaform Cream Nystatin 100,000 i.u./g and Chlorhexidine hydrochloride 1% w/w

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, ask your doctor or pharmacist.**
- **This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.**
- **If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.**

What is in this leaflet

1. What Nystaform Cream is and what it is used for
2. What you need to know before you use Nystaform Cream
3. How to use Nystaform Cream
4. Possible side effects
5. How to store Nystaform Cream
6. Contents of the pack and other information.

1. WHAT NYSTAFORM CREAM IS AND WHAT IT IS USED FOR

Nystaform Cream is a light yellow cream for application to the skin. It is used to treat skin infections caused by either fungi and/or bacteria, such as ringworm, athlete's foot and infected nappy rash.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NYSTAFORM CREAM

Do not use Nystaform Cream

- If you are allergic to nystatin, chlorhexidine hydrochloride or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Nystaform Cream.

Nystaform Cream may in rare cases cause severe allergic reactions, leading to a drop in blood pressure and even to unconsciousness. Early symptoms of a severe allergic reaction may be skin rash or asthma. If you notice these symptoms, stop using Nystaform Cream and contact your doctor as soon as possible (see under section 4).

Take special care with Nystaform Cream

- Nystaform Cream is for **external** use only and should not be used near your eyes, mouth or be swallowed.
- If swallowed accidentally, seek medical advice immediately.
- If Nystaform Cream gets in your eyes accidentally, you should rinse your eyes immediately and contact your doctor.

If you are unsure about anything, please ask your doctor or pharmacist.

Other medicines and Nystaform Cream

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy and breast-feeding and fertility

Do not use Nystaform Cream if you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Important information about some of the ingredients of Nystaform Cream

Nystaform Cream contains cetostearyl alcohol

Nystaform Cream contains the ingredient cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis) in some patients.

3. HOW TO USE NYSTAFORM CREAM

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For application to the skin only.

Apply the cream to the infected area two or three times daily.

The cream should be applied for one week after your infection has healed.

If the infected area has not improved within seven days of starting treatment, consult your doctor.

If the condition does not improve within 14 days of starting treatment, or if a new infection appears, you should stop using Nystaform Cream and consult your doctor. An alternative treatment may be needed.

If you forget to use Nystaform Cream

Apply the cream as soon as you remember and then continue the rest of your treatment as usual.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following reactions **stop using** Nystaform Cream and get immediate medical help:

Swelling of the face, lips, tongue or throat; a red itchy skin rash; wheezing or difficulty breathing; feeling faint and dizzy; a strange metallic taste in the mouth; collapse. You may be having an allergic reaction.

If you develop a rash or your skin becomes itchy, red, dry or inflamed where you have used this medicine, stop using it and talk to your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NYSTAFORM CREAM

Keep this medicine out of the sight and reach of children.

Do not store above 25°C

Do not use this medicine after the expiry date which is stated on the tube and on the carton after EXP. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Nystaform Cream contains

- The active substances are nystatin (100,000 i.u./g), chlorhexidine hydrochloride (1% w/w).
- The other ingredients are benzyl alcohol, cetostearyl alcohol, cetyl esters wax, octyldodecanol, polysorbate 60, sorbitan stearate and purified water.

What Nystaform Cream looks like and contents of the pack

Nystaform Cream is a light yellow cream which comes in 30g aluminium tubes.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Typharm Ltd, 14D Wendover Road, Rackheath Industrial Estate, Norwich, NR13 6LH.

Manufacturer

PURNA PHARMACEUTICALS NV/SA, Rijksweg 17, 2870 Puurs, Belgium

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