

Nystaform HC Cream

Nystatin 100,000 i.u./g, Chlorhexidine hydrochloride 1% w/w, Hydrocortisone 0.5% 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 HC Cream is and what it is used for
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1. WHAT NYSTAFORM HC CREAM IS AND WHAT IT IS USED FOR

Nystaform HC 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.

Corticosteroid creams, ointments and other topical preparations come in four different potencies or strengths. These are known as mild, moderately potent, potent or very potent. Healthcare professionals will usually refer to topical corticosteroid potency rather than strength. A potent or strong corticosteroid has a much stronger effect than a mild corticosteroid when using the same amount. The percentage of active ingredient that is sometimes included on product packaging does not indicate potency. Hydrocortisone is classed as a mild corticosteroid. Your healthcare professional will prescribe or advise a steroid of the appropriate potency for your condition.

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

Do not use Nystaform HC Cream

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

Warnings and precautions

Talk to your doctor or pharmacist before using Nystaform HC Cream.

Nystaform HC 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 HC Cream and contact your doctor as soon as possible (see under section 4).

Take special care with Nystaform HC Cream

- Nystaform HC 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 HC Cream gets in your eyes accidentally, you should rinse your eyes immediately and contact your doctor.
- Use Nystaform HC Cream on large areas of your skin only if told to do so by your doctor, as the hydrocortisone (steroid) may be absorbed into your bloodstream.
- Take care not to cover the treated area of skin with tight clothes or bandages, as this may also cause the hydrocortisone (steroid) to be absorbed into your bloodstream.

If there is a worsening of your condition during use consult your prescriber – you may be experiencing an allergic reaction, have an infection or your condition requires a different treatment. If you experience a recurrence of your condition shortly after stopping treatment, within 2 weeks, do not restart using the cream/ointment without consulting your prescriber unless your prescriber has previously advised you to do so. If your condition has resolved and on recurrence the redness extends beyond the initial treatment area and you experience a burning sensation, please seek medical advice before restarting treatment.

Children

- Use Nystaform HC Cream with care in infants. As Nystaform HC Cream contains hydrocortisone (steroid), long term continuous use in infants should be avoided.

Other medicines and Nystaform HC Cream

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

Pregnancy, breast-feeding and fertility

Do not use Nystaform HC 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 HC Cream

Nystaform HC Cream contains cetostearyl alcohol

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

Nystaform HC Cream contains benzyl alcohol

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

3. HOW TO USE NYSTAFORM HC 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.

Continue treatment for a **maximum of seven days**.

If you forget to use Nystaform HC 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 HC 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 the product, stop using it and talk to your doctor or pharmacist.

If a new infection appears, stop using Nystaform HC Cream and consult your doctor. An alternative treatment may need to be used.

Steroid withdrawal reaction: If used over prolonged periods a withdrawal reaction, which might appear to be different from the previous condition, may occur in some patients during treatment or within days to weeks after stopping treatment with some or all of the following features: redness of the skin which can extend beyond the initial area treated, a burning or stinging sensation, intense itching, peeling of the skin, oozing open sores.

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 or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE NYSTAFORM HC CREAM

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

Do not store above 25°C.

Do not use Nystaform HC Cream 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 HC Cream contains

- The active substances are nystatin (100,000 i.u./g), chlorhexidine hydrochloride (1% w/w) and hydrocortisone (0.5% w/w).
- The other ingredients are cetostearyl alcohol, octyldodecanol, polysorbate 60, sorbitan stearate, cetyl esters wax, benzyl alcohol and purified water.

What Nystaform HC Cream looks like and contents of the pack

Nystaform HC Cream is a light yellow cream which comes in aluminium tubes of 15g and 30g. Not all pack sizes may be available.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder

Typharm Ltd, Unit 1, 39 Mahoney Green, Rackheath, Norwich, NR13 6JY.

Manufacturer

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

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