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| Title: | Nystatin Ointment PIL 30g | Colours (Printed)  Colours (Non printed)  |
| Ref: | Nysta/TY | |
| Date: | 12/11/15 | |
| Size (mm): | 148(W) x 300(H) | |
| Modified: | 02/02/24 | |



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PACKAGE LEAFLET: INFORMATION FOR THE USER

Nystatin/Chlorhexidine acetate/Hydrocortisone 100,000 units/g/1%/1% Ointment

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 Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment is and what it is used for
2. What you need to know before you use Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment
3. How to use Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment
4. Possible side effects
5. How to store Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment
6. Contents of the pack and other information

1. WHAT NYSTATIN/CHLORHEXIDINE ACETATE/HYDROCORTISONE OINTMENT IS AND WHAT IT IS USED FOR

Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment is a light yellow ointment 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 NYSTATIN/CHLORHEXIDINE ACETATE/HYDROCORTISONE OINTMENT

Do not use Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment

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

Warnings and precautions

Do not smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard.



Washing clothing and bedding may reduce product build-up but not totally remove it.

Talk to your doctor or pharmacist before using Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment. Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment 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 Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment and contact your doctor as soon as possible (see under section 4).

Take special care with Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment

- Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment 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 Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment gets in your eyes accidentally, you should rinse your eyes immediately and contact your doctor.
- Use Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment 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.

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Children

- Use Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment with care in infants. As Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment contains hydrocortisone (steroid), long term continuous use in infants should be avoided.

Other medicines and Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment

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

Pregnancy and breast-feeding

Do not use Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment 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.

3. HOW TO USE NYSTATIN/CHLORHEXIDINE ACETATE/HYDROCORTISONE OINTMENT

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 ointment to the infected area two or three times daily.

Continue treatment for a maximum of seven days.

If you forget to use Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment

Apply the ointment 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** Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment 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 medicine, stop using it and talk to your doctor or pharmacist.

If a new infection appears, stop using Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment and consult your doctor. An alternative treatment may need to be used.

Steroid withdrawal reaction: If used for 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 Scheme 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 NYSTATIN/CHLORHEXIDINE ACETATE/HYDROCORTISONE OINTMENT

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

Do not store above 25°C.

Do not use Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment 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 Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment contains

- The active substances are nystatin (100,000 units/g), chlorhexidine acetate (1% w/w) and hydrocortisone (1% w/w).
- The other ingredient is white soft paraffin.

What Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment looks like and contents of the pack

Nystatin/Chlorhexidine acetate/Hydrocortisone Ointment is a light yellow ointment which comes in 30g aluminium tubes.

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.

This leaflet was last revised in January 2024.