PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S1

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

NYSTACID OINTMENT

100 000 units per gram

Ointment

Read all of this leaflet carefully because it contains important information for you

NYSTACID OINTMENT is available without a doctor's prescription, for you to treat a mild illness. Nevertheless you still need to use NYSTACID OINTMENT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share NYSTACID OINTMENT with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

WHAT NYSTACID OINTMENT CONTAINS

The active substance is nystatin.

The other ingredient is plastibase.

WHAT NYSTACID OINTMENT IS USED FOR

NYSTACID OINTMENT is a member of the group of medicines called anti-fungal antibiotics.

NYSTACID OINTMENT is used for skin infections which are caused by yeasts and fungi.

BEFORE YOU USE NYSTACID OINTMENT

Do not use NYSTACID OINTMENT:

- If you are hypersensitive (allergic) to active or any of the other ingredients of NYSTACID OINTMENT.

Pregnancy and breastfeeding

Safety of NYSTACID OINTMENT has not been established.

If you are pregnant or breastfeeding, please consult your doctor, pharmacist or other healthcare professional for advice before using this medicine.

Using other medicines with NYSTACID OINTMENT

NYSTACID OINTMENT does not usually interact with other medicines but, always tell your healthcare professional if you are using any other medicines (this includes complementary or traditional medicines).

HOW TO USE NYSTACID OINTMENT

Do not share medicines prescribed for you with any other person.

Always use NYSTACID OINTMENT exactly as your doctor or pharmacist has instructed you. You should check with your doctor or pharmacist if you are unsure.

Apply a small quantity twice daily to the affected areas or as directed by the doctor or pharmacist and until your infection has cleared up.

If you have the impression that the effect of NYSTACID OINTMENT is too strong or too weak, tell your doctor or pharmacist.

If you use more NYSTACID OINTMENT than you should

Overdosage should not cause any problems. If swallowed, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you missed a dose of NYSTACID OINTMENT

If you forget to use your ointment, apply it as soon as you remember. However, if it is nearly time for your next application, skip the missed dose and continue as before.

POSSIBLE SIDE EFFECTS

Not all side effects reported for NYSTACID OINTMENT are included in this leaflet.

NYSTACID OINTMENT can have side effects.

Should your general health worsen or if you experience any untoward effects while using NYSTACID OINTMENT, please consult your doctor, pharmacist or other health care provider for advice.

If any of the following happens, stop using NYSTACID OINTMENT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- extremely serious allergic skin reaction,
- blistering of the skin, mouth, eyes and genitals as these may be a condition called

Stevens-Johnsons syndrome.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to NYSTACID OINTMENT. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

The following side effects have been reported less frequently:

- inflammation of the skin,
- itching of skin,
- rash.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: https://www.sahpra.org.za/health-products-vigilance/

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088/ +27(0)11 239-6200

By reporting side effects, you can help provide more information on the safety of NYSTACID OINTMENT.

STORAGE AND DISPOSING OF NYSTACID OINTMENT

Store at or below 25 °C.

Protect from light.

Keep the container tightly closed.

Keep in original packaging until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

PRESENTATION OF NYSTACID OINTMENT

15 g is packed in an aluminium, collapsible tube sealed with a white self piercing high density polyethylene cap, and placed in a unit cardboard carton together with a leaflet.

IDENTIFICATION OF NYSTACID OINTMENT

A smooth yellow unctuous mass.

REGISTRATION NUMBER

L/20.1.6/394

NAME AND ADDRESS OF REGISTRATION HOLDER

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

DATE OF PUBLICATION

Date on registration certificate: 17 October 1983

Date of most recently revised approved professional information: 18 June 2020

Namibia: NS1 90/20.1.6/001086

Zimbabwe: P. 91/14.1.3/2541

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

https://www.sahpra.org.za/pi-pil-repository/

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

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