

Package leaflet: Information for the patient

Nystatin ABR 100 000 IU/g cream

nystatin

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 ABR is and what it is used for
2. What you need to know before you use Nystatin ABR
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1. What Nystatin ABR is and what it is used for

Nystatin ABR is an antifungal antibiotic for use on the skin. It stops the growth of fungi and in some cases destroys them.

Nystatin ABR is used for topical treatment of infections of the skin and semi-mucosa caused by fungi, called Candida, such as:

- Angular cheilitis (break-up of the angles of the mouth)
- Erosion in the interdigital folds of the hands;
- Candida perionixis (fungal infection around the nails)
- Candidal balanitis and vulvitis (fungal infection of the external genitalia in men and women)
- Dermatitis caused by diapers in infants
- Fungal infections after prolonged treatment with antibiotics or suppressed immunity

2. What you need to know before you use Nystatin ABR

Do not use Nystatin ABR if:

- you are allergic to nystatin or any of the other ingredients of this medicine (listed in section 6);

Warnings and precautions

Talk to your doctor or pharmacist before using Nystatin ABR.

Parahydroxybenzoate (an excipient contained in this product) may cause contact dermatitis (inflammation of the skin) and urticaria.

In case of hypersensitivity – exacerbated itching, redness and oedema as well as visible worsening of your condition, treatment should be stopped and the therapeutic scheme revisited.

The medicinal product is intended for external use only.

Do not use occlusive dressing.

Do not allow direct contact between your eye(s) and the cream or eye(s) and your hands contaminated with the cream.

Other medicines and Nystatin ABR

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

No drug interactions have been observed.

Nystatin ABR with food and drink

The product is intended for use on the skin.

Pregnancy and breast-feeding

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.

Nystatin ABR is not systemically absorbed and therefore can be used during pregnancy and breastfeeding.

Driving and using machines

Nystatin ABR has no influence on the ability to drive and use machines.

Nystatin ABR contains parabenes

The product contains methyl and propyl parahydroxybenzoate as excipients. They cause contact dermatitis (delayed allergic reaction), and rarely immediate reactions such as urticaria, difficulty breathing or wheezing.

3. How to use Nystatin ABR

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

Nystatin ABR cream should be applied on the skin 2 or 4 times daily. The cream should be applied on areas of inflamed skin as well as onto 5-10 mm of the adjacent area, which is visibly intact. Treatment should continue for at least 2-3 days after resolution of clinical symptoms.

The cream as a dosage form is easier to apply on hairy areas and creases, on the face, as well as in acute inflammatory changes with a tendency to exudate and wet.

If you use more Nystatin ABR than you should

There are no data on overdose with the product and no toxicity data.

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

4. Possible side effects

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

Nystatin ABR cream is very well tolerated. Single cases of severe skin reactions (exanthemoid pustulosis, erythema multiforme following sensitization with oral nystatin) have been described in medical literature. One publication discussed that allergic reactions to nystatin are rare, however, if applied to inflamed skin, systemic absorption and sensitization may occur.

There are no data on adverse drug reactions.

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

Bulgarian Drug Agency
8 Damyan Gruev Street
1303 Sofia
Tel. +359 28903417
Website: www.bda.bg

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

5. How to store Nystatin ABR

Store below 25°C.

Shelf life after first opening: 3 months when stored below 25°C.

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

Do not freeze.

Do not use this medicine after the expiry date which is stated on the carton. 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 ABR contains

- The active substance is nystatin. 1 g cream contains 100 000 IU nystatin.
- The other ingredients are: sodium hexametaphosphate; glycerol; methyl parahydroxybenzoate; propyl parahydroxybenzoate; paraffin, white soft (white petrolatum); stearic acid; cetyl alcohol; self-emulsifying glyceryl monostearate; polysorbate 60; sorbitan stearate; purified water.

What Nystatin ABR looks like and contents of the pack

Homogenous creamy mass of yellow colour.

Nystatin ABR 100 000 IU/ g cream, 15 g in aluminium tubes, laquered, sealed with plastic screw cap. 1 (one) tube with a package leaflet in a carton box.

Marketing Authorisation Holder

Antibiotic-Razgrad AD
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7200 Razgrad, Bulgaria

Manufacturer

Antibiotic-Razgrad AD
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