

Package leaflet: Information for the user

Aciclovir ABR 50 mg/g cream

Aciclovir

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

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 4-5 days.

What is in this leaflet

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

Aciclovir ABR cream is a medicinal product which contains antiviral active ingredient. It is active against the viruses that cause cold sores on the lips and face in humans.

Aciclovir ABR cream is used to treat initial and recurrent herpes of the lips and face.

If you feel unwell after 4-5 days or your condition worsens, you should seek medical attention.

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

Do not use Aciclovir ABR cream if you are allergic (hypersensitive) to aciclovir, valaciclovir, propylene glycol or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

This product should not be applied to the mucous membranes of the mouth and vagina because there is a risk of irritation.

It is for skin use only. Ensure the cream does not get into the eyes.

Patients with impaired immunity (eg patients with HIV infection, AIDS or patients who have undergone bone marrow transplantation) should consult a physician when using this product and the need for concomitant treatment with the tablet formulation or with other antiviral medicinal products should be considered. If you have impaired immunity, consult your doctor if you get an infection.

Before and after using the product, wash your hands thoroughly to avoid worsening the condition or transmitting the infection.

Other medicines and Aciclovir ABR

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines without prescription.

There are no reports of adverse interactions of acyclovir with other medicines. However, concomitant use with other creams or ointments is not recommended, as they may alter the balanced composition of the cream and the action of the active substance.

Aciclovir ABR with food and drink

There are no limitations.

Pregnancy, breast-feeding and fertility

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.

Pregnancy

Aciclovir ABR cream may be used by pregnant women only if the doctor has considered the need for its use and has evaluated the potential risk to the fetus.

Breastfeeding

Aciclovir ABR cream may be used during breast-feeding if the instructions for use provided in this leaflet are met.

Driving and using machines

It does not adversely affect the ability to drive and use machines.

Aciclovir ABR contains propylene glycol and cetostearyl alcohol

Propylene glycol can cause skin irritation.

Cetostearyl alcohol can cause local skin reactions (eg contact dermatitis).

3. How to use Aciclovir ABR

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

Adults and children

Aciclovir ABR cream should be carefully applied as a thin layer on the affected skin, 5 times a day for 4 hours; it should not be applied at night. The duration of treatment is about 5 days (at least 4 days) and in the absence of sufficient effect it can be extended up to 10 days. If, after 10 days of application, complaints persist, consultation with a physician is required.

The product is applied to both affected skin and skin areas where the first signs, such as itching and/or redness, have appeared.

In case of recurrent infections, treatment should start as soon as possible after the first signs appear.

Elderly patients

There are no special requirements for adjustments to the usual dose and route of administration.

If you use more Aciclovir ABR than you should

If you have used more than the recommended dose, talk to your doctor or pharmacist for advice, although there are no data on overdose with this medicine even during accidental ingestion of the contents of the pack.

If you forget to use Aciclovir ABR

If you have missed a dose, take it as soon as you remember, to allow the medicine to act as expected.

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

4. Possible side effects

Like all medicines, Aciclovir ABR can cause side effects, although not everybody gets them. Aciclovir ABR is usually well tolerated.

The frequency of the reported side effects is shown below.

Uncommon (may affect less than one in 100 users)

- Transient burning or stinging at the application site, mild drying or flaking of the skin, itching.

Rare (may affect less than one in 1000 users)

- Flushing, contact dermatitis after administration.

When conducting sensitivity tests, it was most often the cause of these reactions was one of the ingredients of the cream, not aciclovir itself.

Very rare (may affect up to 1 in 10000 users)

- Allergic reactions: immediate type hypersensitivity reactions, incl. angioedema (oedema of the face, lips, tongue and throat) and urticaria.

If any of the side effects get serious or if you experience a side effect not listed in this leaflet, 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

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 Aciclovir ABR

Store below 25°C.

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

Do not use Aciclovir ABRt after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.

Expiry date after first opening: 28 days

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 Aciclovir ABR contains

- The active substance in 1 g cream is aciclovir 50 mg.
- The other ingredient is poloxamer 407, cetostearyl alcohol, sodium lauryl sulfate, white soft paraffin, liquid paraffin, propylene glycol, dimethicone 20, glycerol monostearate and polyoxyethylene stearate mixture, sodium hydroxide (for pH adjustment), purified water

What Aciclovir ABR looks like and contents of the pack

Aciclovir ABR is a white to off white homogenous creamy mass.

Aciclovir ABR 50 mg/g is available in a 5 g and 10 mg aluminium tubes.
One tube is packed into a carton box.

Marketing Authorisation Holder

Antibiotic-Razgrad AD
68 Aprilsko Vastanie Blvd., office 201
7200 Razgrad, Bulgaria

Manufacturer

Antibiotic-Razgrad AD
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For additional information about this medicinal product, please contact the local representative of the Marketing Authorization Holder:

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