Package leaflet: Information for the user

Aciclovir Actavis 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 10 days of treatment. See section 4.

What is in this leaflet

1. What Aciclovir Actavis is and what it is used for

This antiherpetic cream contains aciclovir as an active substance, which has a strong antiviral effect. Herpes is a disease caused by the *Herpes simplex* virus (HSV) and the *Varicella zoster* virus (VZV). After the active substance penetrates the cell infected by the herpes virus, the reproduction of the virus discontinues. At the same time, there is no effect on the healthy cells.

Indications. *Herpes simplex* virus infection on skin and lips (*Herpes labialis*).

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

Do not use Aciclovir Actavis
- if you are allergic to aciclovir, valaciclovir, propylene glycol or any of the other ingredients of this medicine (listed in section 6);
- orally or on genitals.

Warnings and precautions
Talk to your doctor or pharmacist before using Aciclovir Actavis cream.

For external use only!
Do not administer in the eye, oral cavity or vagina. May cause irritation when administered to mucosal membranes.
Do not swallow the cream!

- Wash hands before and after cream application!
- Avoid contact with eyes! In case of eye contact, rinse thoroughly with water.
- Do not break the blisters or remove the crust!

- Avoid transferring the infection, i.e. contact of disease lesions with other people, especially children.
- Systemic treatment should be used in the case of oral mucosal infection and frequent occurrence of blisters. In such cases consult your doctor.
- Treatment with aciclovir cream is not recommended for patients with immune deficiency (e.g. patients with AIDS or patients who have had a bone marrow transplant). In case of severe immune deficiency, treatment with orally administered pharmaceutical forms should be considered. Patients with immune deficiency should consult a doctor when any infection occurs.
- The excipient propylene glycol may cause skin irritation and the excipient cetyl alcohol may cause local skin reactions (incl. contact dermatitis).

Other medicines and Aciclovir Actavis
Although clinically significant interactions have not been observed, please inform your doctor or pharmacist if you are taking or have recently taken any other medicines.

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.
There are insufficient data about the use of the medicine during pregnancy; therefore, Aciclovir Actavis cream should be used with caution during pregnancy.

Driving and using machines
Not applicable.

Aciclovir Actavis contains cetostearyl alcohol
May cause local skin reactions (eg contact dermatitis).

Aciclovir Actavis contains sodium laurilsulfate
This medicine contains 7.5 mg of sodium lauryl sulphate per gram of cream.
Sodium lauryl sulphate may cause local skin reactions (eg tingling or burning sensation) or exacerbate skin reactions in other areas caused by other medicines.

Aciclovir Actavis contains propylene glycol
This medicine contains 400 mg of propylene glycol per gram of cream.
Propylene glycol may cause skin irritation.

3. How to use Aciclovir Actavis

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

Posology
Treatment should be started as soon as possible after the infection starts! It is especially important to start the treatment after the first signs of the disease (characteristic itching) appear or the lesions primarily develop if this is a recurrent episode.
The treatment can also be initiated at later stages after the papule or blister has formed. When crusting occurs, the aciclovir cream is no longer effective.

Adults, including elderly
The cream is applied 5 times a day at 4-hour intervals (except at night). The cream should be applied to the skin in a sufficient amount to properly cover the region affected by the disease.
Treatment duration is 4 days, and up to 10 days, if required, when the treatment has not

produced sufficient results,. If the disease has not healed completely or becomes worse after 10 days of treatment, consult your doctor.
The use of aciclovir cream does not eliminate the virus from the body or reduce the frequency of blister recurrence.

If you feel that the effect of Aciclovir Actavis cream is too strong or too weak, talk to your doctor or pharmacist.

If you use more Aciclovir Actavis cream than you should
No unfavourable effects have been observed with overdose.

If you forget to use Aciclovir Actavis cream
Do not use a double dose to make up for a forgotten cream dose.

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.

The following frequency categories associated with the side effects are estimates.
In most cases there are no data to evaluate frequency. In addition, the side effects may vary depending on the indication.

The following convention has been used for the classification of the frequency of side effects:
Very common ≥ 1/10,
Common ≥1/100 and <1/10,
Uncommon ≥1/1,000 and <1/100,
Rare ≥1/10,000 and <1/1,000,
Very rare < 1/10,000.

Skin and subcutaneous tissue disorders:
Uncommon: transient tingling, prickling, mild dryness of skin, scaling and itching may occur after cream application.
Rare: contact dermatitis and redness. Rash recedes after the treatment is stopped.
According to sensitivity testing, the side effects are more often caused by the excipients than aciclovir.

Immune system disorders:
Very rare: immediate hypersensitivity reactions, including angioedema (swelling of face, tongue and larynx) and hives.

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

5. How to store Aciclovir Actavis

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

Do not store above 25ºC.

Do not use this medicine after the expiry date which is stated on the carton and tube. 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 Aciclovir Actavis contains
- The active substance is aciclovir. 1 g of cream contains 50 mg of aciclovir.
- The other excipients are: poloxamer 407, cetostearyl alcohol, sodium lauryl sulphate, white vaseline, liquid paraffin, propylene glycol, dimethicone, mixture of glycerol monostearate and polyoxyethylene stearate, purified water and sodium hydroxide.

What Aciclovir Actavis cream looks like and contents of the pack
50 mg/g cream, 5 g or 10 g in a tube.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Marketing authorisation holder
Actavis Group PTC ehf
Reykjavikurvegi 76-78
220 Hafnarfjördur
Iceland

Manufacturer
Balkanpharma-Razgrad AD.,
68 "Aprilsko vastaine" blvd,
Razgrad,
Bulgaria

For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder:
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