

Package leaflet: Information for the patient

Aciclovir ratiopharm 50 mg/g, crème

aciclovir

Rx:

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.

OTC:

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 have 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 x days](#).

What is in this leaflet

1. What Aciclovir cream is and what it is used for
2. What you need to know before you use Aciclovir cream
3. How to use Aciclovir cream
4. Possible side effects
5. How to store Aciclovir cream
6. Contents of the pack and other information

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

Aciclovir is an antiviral agent.

Aciclovir cream is applied to the skin to treat herpes simplex virus infections, including first and repeated attacks of genital herpes and herpes of the lips (cold sores).

You must talk to your doctor if you do not feel better or if you feel worse after 10 days.

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

Do not use Aciclovir cream

- if you are **allergic to aciclovir, valaciclovir, propylene glycol or any of the other ingredients** of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before using Aciclovir cream

- if you apply Aciclovir cream. Aciclovir cream is only suitable for **external use** (on the skin) on or around the lips or the genitals. The cream is not suitable for use on the mucous membranes, such as in the mouth, eye or vagina.
- if Aciclovir cream comes in contact with your **eyes**. Should the cream come into contact with the eyes, rinse them with plenty of cold water. Contact your doctor if your eyes get sore afterwards.
- if **blisters** have formed on your skin. Since herpes infections are contagious, it is advisable to avoid contact with the infected skin, especially when blisters have been formed. After applying Aciclovir cream to the skin infection, it is advisable to wash your hands, to prevent contamination of other parts of the body (e. g. the eyes).
- if you have a **seriously impaired immune system**. The seriousness of the infection is determined by a large number of factors, including the extent to which the immune system reacts to an infection. If your immune system is seriously impaired, it is advisable to consult a doctor before you start using the cream as you may need to take aciclovir tablets. Therefore, you should inform your doctor about your case history as completely as possible so he/she can determine the best therapy for you;
- if you have **visible lesions**. There is a chance that your partner gets infected with a herpes infection of the genitals (herpes genitalis). You should refrain from sexual intercourse until any lesions have healed.

Other medicines and Aciclovir cream

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

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.

Pregnancy

Safe use of Aciclovir cream during pregnancy has not been established, however the systemic exposure to aciclovir from topical application of Aciclovir cream is very low.

A pregnancy registry has not shown an increase in the number of birth defects, or uniqueness or a consistent pattern of birth defects.

Animal studies have revealed harmful effects but only following such high subcutaneous doses that maternal toxicity was produced. The significance of these findings for humans is not clear.

You should only use Aciclovir cream when your doctor has advised you to do so.

Breast-feeding

Aciclovir does pass into breast milk following systemic administration. However, the dosage received by a nursing infant following maternal use of Aciclovir cream would be insignificant.

You should only use Aciclovir cream when your doctor has advised so.

Driving and using machines

An effect is unlikely.

Aciclovir cream contains propylene glycol

This medicine contains 250 mg propylene glycol in each g.

Propylene glycol may cause skin irritation.

Aciclovir cream contains cetyl alcohol

May cause skin irritation (e. g. contact dermatitis) (see section 4).

3. How to use Aciclovir cream

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

The recommended dose is

Treatment with Aciclovir cream should start as soon as you feel a skin infection coming up or as soon as possible after the skin infection has developed.

Usually you can feel the skin infection coming (up) because the skin starts to itch locally or hurt, becomes numb or inflamed. **When such signs develop, Aciclovir cream should be applied to the affected areas as soon as possible.**

Application of the cream is only useful as long as new blisters are formed. When the blisters have dried out or scabs have been formed, treatment with the cream is no longer effective.

Method and/or route(s) of administration

Press the desired amount of cream from the tube and apply it gently to the areas where you feel the blisters coming up or where blisters have developed.

Wash your hands before and after you use your cream. Always close the tube well after use.

Frequency of administration

The cream is applied to the affected skin on or around the lips or genitals five times a day, with intervals of about four hours. At night the treatment does not have to be continued.

Duration of treatment

A complete treatment takes/lasts five days and should be continued to the end. If the skin infection has not cleared up by then, the treatment may be prolonged for another five days. If the skin infection has not cleared up after two complete treatments, it is advisable to contact your doctor again.

If you use more Aciclovir cream than you should

If you have used too much Aciclovir cream, contact your physician or pharmacist. You are very unlikely to suffer any bad effects, if you accidentally swallow Aciclovir cream, but if you notice any unusual effects or are worried contact your doctor.

If you forget to use Aciclovir cream

If you have forgotten to use Aciclovir cream, apply it as soon as you remember and then apply the next treatment at the usual time. However, if you discover the forgotten dose close to your next dose, continue the normal dosing schedule like nothing happened. Do not take a double dose to make up for a forgotten dose.

If you stop using Aciclovir cream

A complete treatment lasts five days and should be continued to the end. If you stop before the 5 day treatment is finished, the virus infection could come back again.

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 side effects have been observed:

Uncommon: may affect up to 1 in 100 people

- a burning feeling or itchy or burning sensation for a short period;
- mild dry, flaking skin;
- itching.

Rare: may affect up to 1 in 1,000 people

- redness of your skin;
- an allergic (hypersensitivity) reaction to aciclovir or one of the other ingredients of the cream, manifesting as an inflammation of the skin (contact dermatitis).

Very rare: may affect up to 1 in 10,000 people

- allergic (hypersensitivity) reactions manifesting as a swelling of your face, lips, tongue or other parts of your body (angioedema) or as;
- rash, itching or hives on your skin (urticaria).

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 national reporting system](#) listed in [Appendix V](#). By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Aciclovir cream

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

Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.

After first opening the cream is to be used within 28 days.

Do not store above 30 °C.

Do not throw away any medicines via wastewater. 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 cream contains

- The active substance is aciclovir.
Each gram of Aciclovir cream contains 50 mg of aciclovir.
- The other ingredients are propylene glycol, white soft paraffin, liquid paraffin, cetyl alcohol, dimeticone, stearyl macroglycerides, and purified water.

What Aciclovir cream looks like and contents of the pack

Aciclovir cream is a soft, white, odourless cream.

Aciclovir cream is available in tubes of 2, 3, 10 or 15 g cream.

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen

ratiopharm GmbH
Graf-Arco-Strasse 3
89079 Ulm
Duitsland

Fabrikant

Merckle GmbH

Ludwig-Merckle-Strasse 3
89143 Blaubeuren
Duitsland

In het register ingeschreven onder
RVG 22285

This medicinal product is authorised in the Member States of the EEA under the following names:

Nederland	Aciclovir ratiopharm 50 mg/g, crème
Portugal	Erpesin

Deze bijsluiter is voor het laatst goedgekeurd in juni 2021