

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Aciclovir Agepha 30 mg/g eye ointment

Active substance: Aciclovir

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?

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1. What Aciclovir Agepha 30 mg/g eye ointment is and what it is used for?

Aciclovir Agepha eye ointment contains a medicine called aciclovir, which belongs to a group of medicines called antivirals.

It is used to treat eye infections caused by the Herpes simplex virus. It works by killing or stopping the growth of viruses on the front of your eyeball (cornea)

2. What you need to know before you use Aciclovir Agepha 30 mg/g eye ointment?

Do not use Aciclovir Agepha 30 mg/g eye ointment,

If you are allergic to aciclovir or valaciclovir 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 Agepha 30 mg/g eye ointment

- Use Aciclovir Agepha 30 mg/g eye ointment only on eye
- You may immediately experience a mild stinging and burning sensation after the application.
- Immediate hypersensitivity reactions, including angioedema, swelling of the face etc. can occur. Contact a doctor immediately in case of such hypersensitivity reactions.
- If you experience allergic reactions such as itching of eyelid, swelling or redness of the eye, discontinue the treatment with Aciclovir Agepha 30 mg/g eye ointment and consult a doctor.
- Please contact your doctor immediately for advice, if any symptoms gets serious or reoccurs.

During the treatment with Aciclovir Agepha 30 mg/g eye ointment, contact lenses should not be worn.

Children and adolescents

Same as in adults.

Other medicines and Aciclovir Agepha 30 mg/g eye ointment

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

When applied locally in the eye, no significant interactions were observed so far.

There is however insufficient information on the use of Aciclovir Agepha eye ointment and simultaneous use with eye medicines containing corticosteroids. Your doctor will decide if this is appropriate for you.

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 using this medicine.

Aciclovir Agepha eye ointment can be used during pregnancy or breast-feeding as when used at recommended doses no side effects are expected during pregnancy, for the foetus or new born child

Driving and using machines

Due to its nature, this medicine may cause temporary vision impairment. Therefore, special care should be taken when driving motor vehicles, when working without secure hold and when operating machinery.

3. How to use Aciclovir Agepha 30 mg/g eye ointment

Instructions for Use

For ocular use

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

Unless otherwise prescribed by a doctor, the recommended dose is:

Place an 1 cm ribbon of ointment inside the lower conjunctival sac 5 times a day (every 4 hours). Suggested times are: **7:00, 11:00, 15:00, 19:00 and 23:00.**

Pull down the lower lid and place the ointment strand inside the conjunctival sac. Close your eye lids, and rotate your eye ball so that the ointment gets better distributed.

It is essential that you apply Aciclovir Agepha 30 mg/g eye ointment during the day in regular intervals of 4 hours to ensure the success of treatment. After the inflammation of the cornea has healed up, the treatment should still be continued for at least 3 days.

Use in children and adolescents

Same as in adults.

If you use more Aciclovir Agepha than you should

Talk to your doctor or pharmacist if you use too much Aciclovir Agepha. Aciclovir Agepha eye ointment is for use in the eye, if you swallow any talk to your doctor or pharmacist.

If you forget to use Aciclovir Agepha 30 mg/g eye ointment

If you forget to use Aciclovir Agepha, use it as soon as you remember. However, if it is nearly time for your next application, skip the missed application. Do not use a double dose to make up for a forgotten dose.

If you stop using Aciclovir Agepha 30 mg/g eye ointment

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

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 Agepha eye ointment can cause side effects, although not everybody gets them.

Immediately after application of the eye ointment, a transient mild stinging or burning may occur. If you notice swelling of the face, angioedema etc, stop using Aciclovir Agepha and see a doctor straight away.

Allergic reactions very rare (may affect less than 1 in 10,000 people))

If you have an allergic reaction or acute hypersensitivity reactions, stop using Aciclovir Agepha and see a doctor straight away.

The signs may include:

- rash, itching or hives on your skin
- swelling of your face, lips, tongue or other parts of your body
- shortness of breath, wheezing or trouble breathing
- unexplained fever (high temperature) and feeling faint, especially when standing up.

Other side effects include:

Very common (may affect more than 1 in 10 people):

burning or irritation, photophobia/light sensitivity or feeling as if there is something in your eye (superficial punctate keratopathy)

This usually does not require cessation of the treatment and heals immediately

Uncommon (may affect up to 1 in 100 people):

transient mild stinging or burning occurring immediately following application

swollen, runny eyes (Conjunctivitis)

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

swollen, red, irritated, itchy eyelids (blepharitis)

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell 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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Aciclovir Agepha 30 mg/g eye ointment?

Store below 25 °C. 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 label and carton. The expiry date refers to the last day of that month. Do not use for more than 4 weeks after first opening.

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 to protect the environment.

6. Contents of the pack and other information

What Aciclovir Agepha 30 mg/g eye ointment contains:

The active substance is Aciclovir. 1g ointment contains 30 mg Aciclovir. The other excipient is White soft paraffin

What Aciclovir Agepha 30 mg/g eye ointment looks like and contents of the pack

1 carton contains one Aluminium tube with polyethylene cap and polyethylene Cannula (tip) containing 4.5g of white to whitish-grey eye ointment.

Marketing Authorisation Holder and Manufacturer

AGEPHA Pharma s.r.o, Diaľničná cesta 5, 903 01 Senec, Slovakia

This leaflet was last revised in March 2019