

Package leaflet: information for the patient**Aciclovir Slavia 50 mg/g cream**

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.
- Ask your physician, your pharmacist or your nurse if you need additional information.
- This medicine has been described only for you. You should not give it to other people. It can harm them, even if they present the same disease symptoms as you.
- If you get any adverse reactions, talk to your physician or your pharmacist or your nurse. This includes any possible adverse reactions not listed in this leaflet. See section 4.

What is in this leaflet

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

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

Aciclovir Slavia is part of the therapeutic group: chemotherapeutics for local use, antivirals

Aciclovir Slavia is used to treat herpetic ulcers and other skin infections caused by the *herpes simplex* virus. It will not be administered in the eyes, inside the mouth, the nose or of the vagina.

2. What you need to know before you use Aciclovir Slavia**Do not use Aciclovir Slavia:**

- if you are allergic to aciclovir or to any other component of this medicine (listed in section 6).

Warnings and precautions

Certain people should not use Aciclovir Slavia. Ask yourself the following before using Aciclovir Slavia:

- Are you pregnant, are you trying to get pregnant or are you breast-feeding?
- Have you previously had an allergic reaction to aciclovir, valaciclovir, propylene glycol or any of the components of the medicine?

If the answer is yes to any of these questions or you are not sure of the answer and have never discussed it with a physician, tell your physician or pharmacist before using the medicine.

Pay special attention and consult your physician if:

- you have conditions that can weaken your immune system, for example, an HIV infection, a bone marrow transplant or undergoing cancer treatment. In this case, an infection of the skin may be more serious for you than for other people.
- you are not sure if you have herpes or not.
- the herpes you are affected by is very serious.
- the herpes you are affected by has not completely healed after 10 days or has worsened.

Do not use Aciclovir Slavia:

- for other skin infections other than herpes;
- to treat genital herpes;
- inside your mouth (for example, for mouth ulcerations), your nose or your vagina.

Inform your physician each time herpes sores appear. Don't use Aciclovir Slavia unless your physician recommends it.

Aciclovir Slavia with other medicines

Please tell your physician or pharmacist if you are taking or have recently taken any other medicines, including those released without medical prescription, with Aciclovir Slavia, even if no clinically significant interactions with other drugs have been identified.

Pregnancy, breastfeeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your physician or pharmacist for advice before taking any medicine.

Driving vehicles and use of machineries

There are no data to suggest that aciclovir influences the ability to drive vehicles or to use machinery.

Aciclovir Slavia contains cetostearyl alcohol

The cetostearyl alcohol in the composition of the drug can cause local adverse reactions of the skin (for example, contact dermatitis).

3. How to use Aciclovir Slavia

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

This medicine is intended for external use only.

Wash your hands every time, before and after using the cream, to avoid the aggravation or transmission of infection.

Aciclovir Slavia works best when it is used from the first signs of the disease (tingling or itching); it is recommended to start treatment as soon as possible. If this is the first *herpes simplex* virus infection, use the cream immediately. If herpetic swelling occurs regularly, start using the cream as soon as you feel the appearance of one. These are manifested by prickling sensations, itching or sharp pains.

Apply a thin layer of cream to the affected area every three to four hours during the day. This means a maximum of 5 times a day. However, always use the cream as advised by your physician. If you are still not sure how to use the cream, ask your physician or pharmacist for advice.

Use Aciclovir Slavia for a period of 4 days. If the ulcers have not healed completely after four days, carefully use the cream further, up to 10 days of treatment, in total. If the ulcers have not healed after ten days, stop using the cream and inform your physician.

Apply enough cream to cover the affected area, including the edges of the blisters if they are present.

If your symptoms persist for more than 10 days, you should consult your physician.

Do not use Aciclovir Slavia inside the mouth, nose or vagina. It can irritate these areas. However, Aciclovir Slavia is not toxic if swallowed.

Do not use the cream for ocular administration. If the cream still reaches the eye, wash with plenty of cold water. If ulcers appear or you are concerned, inform your physician.

Do not mix Aciclovir Slavia with other skin lotions or creams.

If you use more Aciclovir Slavia than you should

No cases of overdose have been reported.

If the contents of a tube are accidentally swallowed, contact your physician.

If you forget to use Aciclovir Slavia

If you forget to use a dose, apply it as soon as you remember. However, if it's time for the administration of the next dose, apply only this one. Do not use a double dose to make up for the missed dose.

If you stop using Aciclovir Slavia

Consult your physician first.

If you have any questions regarding this medicine, talk to your physician, pharmacist or nurse.

4. Possible adverse reactions

Like all medicines, Aciclovir Slavia can cause adverse reactions, even though they do not occur in all patients.

Some people may be allergic/sensitive to Aciclovir Slavia. There have been rare cases of allergic reactions, including swelling especially of the lips, face and/or eyelids, redness of the integuments or sore swelling of the skin, hives. If you have any of these symptoms, inform your physician immediately and stop using the cream until your physician or pharmacist tell you otherwise.

Aciclovir Slavia may cause stinging or a slight burning sensation when you apply it for the first time. Certain people may feel their skin dry or too soft, they may have sensations of slight stinging or may notice redness of the skin. If any of these adverse reactions upset you, inform the physician.

Reporting of side effects

If you get any adverse reactions, talk to your physician or pharmacist. These include any possible adverse reactions not listed in this leaflet. Also, you can report adverse reactions directly through the national reporting system, details of which are published on National Agency for Medicines and Medical Devices of Romania web-site <http://www.anm.ro/>.

By reporting adverse reactions, you can help provide additional information about the safety of this medicine.

5. How to store Aciclovir Slavia

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 package, after EXP. The expiry date refers to the last day of that month.

Store at temperatures lower than 25°C, in the original package.

Use within 6 weeks after first opening of the tube.

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 does Aciclovir Slavia contain

- The active substance is micronized aciclovir. Each gram of cream contains 50 mg of micronized aciclovir.
- The other components are: cetostearyl alcohol, emulsifying cetostearyl alcohol (type A), white Vaseline, liquid paraffin, benzyl alcohol, purified water.

What Aciclovir Slavia looks like and contents of the pack

Aciclovir Slavia comes in the form of a semi-solid, homogeneous, unctuous, white mass.

It is available in two packaging forms:

- Box with one aluminum (Al) tube, sealed with aluminum membrane, closed with a high density polyethylene (HDPE) threaded cap, equipped with membrane perforation system; the tube contains 15 g of cream.
- Box with one aluminum (Al) tube, equipped with an injector type applicator, closed with a high density polyethylene (HDPE) threaded cap; the tube contains 5 g of cream.

Marketing authorisation holder

S.C. Slavia Pharm S.R.L.

44C Theodor Pallady Blvd., 032266, Bucharest, Romania

Manufacturer

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44C Theodor Pallady Blvd., 032266, Bucharest, Romania

This leaflet was revised in August 2022.

Additional information about this medicine is available on National Agency for Medicines and Medical Devices of Romania web-site <http://www.anm.ro/>