

PACKAGE LEAFLET: INFORMATION FOR THE USER

HERPLEX

50 mg/1 g cream

ACICLOVIR

• This leaflet is a copy of the Summary of Product Characteristics and Patient Information Leaflet for a medicine, which outlines the conditions under which the medicine should be used and information on its known safety • The product information may be updated several times within its shelf life, and there could be differences between the version of information shown here and other information in the public domain or in the package insert • This leaflet may not contain all the information about the medicine or the information may not be the most up to date version for this product • If you have any questions or are not sure about anything, ask your doctor or pharmacist • Read all of this leaflet carefully before you start taking 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 •

What is in this leaflet?

1. What Herplex is and what it is used for
2. Before you take Herplex
3. How to take Herplex
4. Possible side effects
5. How to store Herplex
6. Further information

1. WHAT HERPLEX IS AND WHAT IT IS USED FOR

HERPLEX CREAM contains acyclovir, an antiviral medicine for local application on the skin.

HERPLEX CREAM is applied for local treatment of skin infections caused by the herpes simplex viruses, including infection of the skin that occurs in the genital area (primary and recurrent herpes genitalis), as well as "the fever" (herpes labialis), an infection of the skin that most often occurs on the lips and the skin around the mouth and nose.

2. BEFORE YOU TAKE HERPLEX

Do not take HERPLEX CREAM:

- If you are hypersensitive to acyclovir, valaciclovir, propylene glycol or some of the other ingredients of the medicine.

Be careful with HERPLEX CREAM:

- If your immune system is weakened due to illness and therefore is less resistant to various infections (for example, if you are suffering from HIV infection or AIDS or have had a bone marrow transplant).

Do not use HERPLEX CREAM on the mucous membranes of the mouth, eye or of the vagina. In case that the cream comes into your eyes, rinse eyes thoroughly with cold water. If you notice symptoms of irritation of the mucous membranes of the eyes, consult a doctor.

If any of the above applies to you, or you are not sure, contact your doctor immediately.

Taking other medicines with HERPLEX CREAM

Tell your doctor about all the medicines you are taking or have recently taken, including those that you bought without a prescription. If you are received in the hospital, inform the competent doctor that you are using Herplex cream as well as any other medicines you are taking.

No interactions with other medicines were observed.

Pregnancy and breastfeeding

Ask your doctor or pharmacist for advice before using any medicine.

The application of HERPLEX CREAM during pregnancy is justified when a possible benefit for a pregnant woman overcomes the possible risks for the fetus.

After topical application of acyclovir on the skin does there is no systemic absorption of the medicine and excretion of significant amounts of the medicine into the breast milk. Therefore Herplex cream, according to the doctor`s decision, can be used during breastfeeding.

Severely immunocompromised patients

In severely immunocompromised patients (eg in patients with AIDS, or in patients after bone marrow transplantation) the use of oral acyclovir should be considered.

3. HOW TAKE HERPLEX

It is important that you use HERPLEX CREAM as determined by your doctor. If you're not sure how you need to use this medicine, consult with your doctor or pharmacist.

Before and after applying the HERPLEX CREAM, be sure to wash your hands.

You need to apply HERPLEX CREAM as early as possible, when the first symptoms appear (e.g., tingling, itching, burning), which usually precede the outbreak of blisters on the skin.

HERPLEX CREAM should be applied to the skin changes or skin changes emerging as early as possible by the onset of the infection. It is particularly important that the treatment of relapses of the disease begins during the prodromal phase or at the first sign of an outbreak of skin changes.

Adults and children

HERPLEX CREAM is applied in a thin layer 5 times a day at intervals of about 4 hours. It is not necessary to apply the cream during the night.

The treatment should last at least 4 days in the case of herpes viral infection of the lips, or 5 days in the case of genital herpes. If after 5 days there is no a complete disappearance of skin changes, you can continue treatment during the next 5 days. If even after this healing does not occur, contact your doctor.

If you use more HERPLEX CREAM than you should

An overdose at the local application of HERPLEX CREAM is not likely, due to the limited absorption of medication through the skin.

HERPLEX CREAM is meant for a local application on the skin. If you accidentally swallow it, talk to your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines HERPLEX CREAM can cause side effects.

The following side effects may occur during use of HERPLEX CREAM:

- allergic reactions (in less than 1 in 10,000 people).

In the event of an allergic reaction (rash, itching, redness, and swelling of the lips, tongue, face or other parts of the body, asphyxia) stop applying HERPLEX CREAM and immediately contact your doctor or go to the nearest medical institution.

Uncommon (less than 1 in 100 people):

- transient stinging and burning sensation of the skin at the site of application
- mild dryness or peeling of skin
- itching.

Rare (less than 1 in 1000 people):

- redness of the skin, swelling and inflammation, blisters (contact dermatitis)
- skin rash.

Reporting suspected side effects of medicine

In case of any adverse reaction following administration of the medicine, you must inform your doctor or pharmacist. This includes all possible adverse reactions that are not listed in this instruction leaflet, as well as those that are.

5. HOW TO STORE HERPLEX

Keep HERPLEX CREAM out of reach and sight of children.

Store at a temperature up to 25 ° c.

Shelf-life:

The expiry date is printed on the packaging.

The expiry date is 2 years from date of manufacture stated on the packaging.

HERPLEX CREAM must not be used after the expiry date which is stated on the carton.

Medicines should not be disposed of via household wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What does HERPLEX CREAM contain?

The active substance is acyclovir.

One gram of cream contains 50 mg of acyclovir.

The other ingredients: propylene glycol; glycerol monostearate and macrogol [100] stearate; cetyl and stearyl alcohol; paraffin, liquid; vaseline, white; sodium laurylsulfate; water, purified.

How HERPLEX CREAM looks like and contents of the pack

HERPLEX CREAM is white in color.

5 or 10 grams of cream in the aluminum tube with the extension, in the box.

Regime of dispensing

The medicine is issued on doctor's prescription

Manufacturer

BELUPO lijekovi i kozmetika, d.d.
Ulica Danica 5
48 000 Koprivnica, Croatia

Manufacturer of the medicinal product

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