

PACKAGE LEAFLET: Information for the user

VIRZIN

Cream – 5%

(Acyclovir)

Read this leaflet carefully before you start using this medicine.

- 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 symptoms are the same as yours.
- If any of the side effects gets worse or if you notice any side effect not listed in this leaflet, please inform your doctor or pharmacist.

What is in this leaflet:

1. What Virzin is and what it is used for
2. Before you use Virzin
3. How to use Virzin
4. Possible side effects
5. How to store Virzin
6. Other information

1. WHAT VIRZIN IS AND WHAT IT IS USED FOR

Virzin contains the active substance acyclovir, which is an inhibitor of the replication of the viral DNA interfering with DNA - polymerase. The doses of Virzin administered locally have a minimal absorption. Acyclovir is excreted by the kidneys through glomerular filtration and tubular secretion.

Virzin cream is used in the initial and recurrent treatment of *Herpes simplex* skin infections, labial and genital.

2. BEFORE YOU USE VIRZIN

Do not use Virzin:

- if you are hypersensitive to acyclovir, or to the other excipients of the cream and if you have any other hypersensitivity history from other antivirals;
- if the patient is a child under 2 years old.

Take special care with Virzin

Virzin cream is only for dermatological use and should not be used in the eye, in the mucous membranes of the mouth or vagina, because it may cause local irritation.

It is not recommended for use by patients who know they are immunocompromised e.g. by HIV infection, bone marrow transplant or cancer treatment, except on the advice of a doctor. Such individuals should be encouraged to consult a physician concerning the treatment of an infection.

Taking other medicines

Please contact your doctor or pharmacist if you are taking / using or have recently taken / used other medicines, including those obtained without a prescription.

Do not forget to inform your doctor for the treatment with Virzin if you have been given any other drug during treatment.

However, clinical experience has not identified any interaction of acyclovir cream as a result of the local or systemic administration of other drugs concomitantly with it.

Pregnancy

Ask for the advice of the pharmacist or of the doctor before using this drug.

Virzin, since it has as active substance acyclovir, should not be used during pregnancy, unless the benefits of the drug justify the risk on the fetus.

Breastfeeding

It is not known yet if after local application of acyclovir cream, the active substance passes or not in breastmilk. Caution should be exercised when this drug is used by mothers that breastfeed babies.

Driving and using machinery

The effect of this drug on the ability to drive and use machinery is harmless.

Important information about some of the excipients of Virzin

This drug contains:

- cetyl alcohol, which may cause local skin reactions (e.g. contact dermatitis);
- propylene glycol, which may cause skin irritation.

3. HOW TO USE VIRZIN

Always use Virzin exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. You should talk to your doctor if you feel that the effects of Virzin cream are too strong or too weak.

For the treatment of the above-prescribed viral infection forms is recommended the application of a sufficient amount of cream to cover completely the lesions, every 4 hours 5 times daily, for 5 days. If after 5 days is not achieved the complete healing, then the treatment should continue for 5 other days. The applied dosage depends on the total surface of the lesions.

Dosage may need to be increased or to be reduced. Your doctor should advice you how to do it. The finger or the rubber glove used for the application of the cream should not touch other parts of the body or other people, because the infection may be transmitted in the touched parts.

Therapy should start as soon as possible. It is especially important that treatment of recurrent episodes begins during the prodromal period or as soon as the symptoms appear.

If you use more Virzin than you should

If you use more Virzin than you should, or if the children have taken this medicine incorrectly, please contact your doctor or call the hospital or emergency to get an opinion for the risk and an advice for the actions to be taken.

Overdose cases are not known because absorption through the skin is minimal.

If you forget to use Virzin

If you forget a dose (or more doses), use the following dose when it is time to use it usually.

Do not use a double dose (or higher) to make up for a forgotten dose (doses).

If you have further questions on the use of this medicinal product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all other drugs, Virzin cream may cause side effects, although not everybody manifests them.

Most side effects are dose-related and disappear when dosage is reduced, or treatment is interrupted. Some side effects happen at the beginning of the treatment and disappear spontaneously with treatment continuance.

The side effects that may appear are:

- drying and flaking of the skin;
- transient stinging or burning;
- pruritus;
- rash.

If any of the side effects gets serious, or if you notice any side effects not mentioned in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE VIRZIN

Keep out of the reach and sight of children.

Do not use Virzin cream after the expiry date which is stated on the package.

Do not store above 25°C.

Keep in the original package to protect it from light.

6. OTHER INFORMATION

What Virzin contains

The active substance is acyclovir.

1 g cream contains 50 mg acyclovir.

The excipients are: glycerolmonostearate and polyethyleneglycol - 30 stearate, dimethicone 350 fluid, cetyl alcohol, white soft paraffin, light liquid paraffin, macrogolglycerololeate, propylene glycol, purified water.

Contents of the pack

Carton box with 1 tube of 15 g.

Marketing Authorisation Holder (MAH) and Manufacturer:

PROFARMA Sh.a,

St. "Skënder Vila",

Tirana, Albania.

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