

INSTRUCTIONS FOR USE

Please read all the instructions for use carefully because they contain important information for you.

This medicine is also available without a doctor's prescription. In order to achieve the best possible success, Supraviran® cream must be used according to instructions.

- Keep this leaflet. You may need to read it again.

- Ask your pharmacist if you require further information or advice.

- If your illness becomes worse or does not improve after ten days, you must consult a doctor.

This package insert tells you:

1. What is Supraviran®, cream and for what is it used?
2. What must you take into account before using Supraviran®, cream?
3. How do you use Supraviran®, cream?
4. What side-effects may occur?
5. How do you store Supraviran®, cream?

Supraviran®, cream



Active substance

The active ingredient is aciclovir.

1 g cream contains 50 mg aciclovir

The other ingredients are:

Macrogol (30) glyceryl monostearate, dimethicone 350, white soft paraffin, cetyl alcohol (Ph. Eur.), liquid paraffin, propylene glycol, purified water.

Supraviran®, cream is available in tubes containing 2 g cream.

1. WHAT IS SUPRAVIRAN®, CREAM AND FOR WHAT IS IT USED?

Supraviran®, cream is a medicine for the treatment of virus infections (virustatic agent).

Marketing Authorisation Holder and Manufacturer

Grünenthal GmbH - 52099 Aachen

Tel. + 49-241 - 569 - 0

Fax + 49-241 - 569 - 1498

Supraviran®, cream is used

to relieve pain and itching in recurrent herpes of the lips (recurrent blisters on the lips caused by herpes simplex viruses).

2. WHAT MUST BE TAKEN INTO ACCOUNT BEFORE USING SUPRAVIRAN®, CREAM?

2.1 Supraviran®, cream must not be used,

- if you are allergic to aciclovir or valaciclovir or any of the other ingredients of Supraviran®, cream.

2.2 Particular caution is necessary when taking/using Supraviran®, cream

- if you suffer from severe disorders of your immune system. In this case you should inform and consult your doctor before using Supraviran®, cream. Supraviran®, cream should not be applied to mucous membranes (e.g. in the mouth, eyes or vagina), otherwise local irritation may occur.

Pregnancy

No sufficient experience on the use of Supraviran®, cream during pregnancy is available. If treatment is necessary during pregnancy, the doctor must carefully weigh up the benefits and the risks.

Breast-feeding

When breast-feeding you may use Supraviran®, cream according to the doctor's instructions. Avoid letting the child come into contact with the treated parts of the body.

Driving and operating machinery

Direct effects of Supraviran®, cream on reactions or road safety are not known.

Important warning on certain ingredients of Supraviran®, cream

Supraviran®, cream should not be diluted or used as a base for absorbing other substances. During treatment with Supraviran®, cream in the genital or anal region the components of the cream white soft paraffin and liquid paraffin may reduce the strength of latex condoms used at the same time, thus affecting their reliability. Propylene glycol may irritate the skin. Cetyl alcohol may cause local skin reactions (e.g. contact dermatitis).

Interactions with Other Medicines

Please inform your doctor or pharmacist if you are taking/using or have recently taken/used other medicines, even if they do not require a prescription. Supraviran®, cream is not known to interact with other medicines.

THIS IS A MEDICAMENT

Medicament is a product, which affects your health and its consumption contrary to instructions is dangerous for you. Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.

- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medicaments out of reach of children.

Council of Arab Health Ministers

Union of Arab Pharmacists

3. HOW DO YOU USE SUPRAVIRAN®, CREAM?

Always apply Supraviran®, cream exactly according to the instructions in this leaflet. You should check with your doctor or pharmacist if you are not quite sure. Unless otherwise prescribed by your doctor, the usual dose is:

The cream should be applied sparingly to the infected skin five times daily every four hours.

Mode of Application

The cream should be applied with the aid of a cotton-wool bud coated with the amount necessary to cover the infected area of skin. On application care should be taken to see that not only the visible signs of herpes (blisters, swelling, redness) are treated with the cream, but also the neighbouring areas. If it is necessary to apply by hand, you should wash your hands thoroughly before and afterwards in order to avoid additional infection of the damaged skin, e.g. by bacteria, or transmission of the viruses to non-infected mucous membranes and skin.

How long should you use Supraviran®, cream?

Your doctor will decide on how long you should use Supraviran®, cream. Please keep to this time even if you feel better.

The duration of treatment is generally five days. If the symptoms become worse during treatment, or the blisters have not become encrusted or healed after 10 days, stop treatment and consult your doctor.

Do not use Supraviran®, cream for more than ten days without consulting your doctor. Please consult your doctor if you feel that the effect of Supraviran®, cream is too strong or too weak.

If you have forgotten to use Supraviran®, cream:

If you forget to apply it once or several times, consult your doctor.

Effects if treatment with Supraviran®, cream is stopped

If you wish to stop treatment on account of side-effects, please consult your doctor so that he/she can prescribe another medicine.

4. WHAT SIDE-EFFECTS MAY OCCUR?

Like all medicines, Supraviran®, cream may have side-effects.

The following terms are used to assess the frequency of side-effects:

Very common more than 1 in 10 people treated	Common more than 1 in 100 people treated
Uncommon more than 1 in 1,000 people treated	Rare more than 1 in 10,000 people treated
Very rare 1 or less in 10,000 people treated, including isolated cases	

Side-effects

Diseases of the skin and subcutaneous tissues

Uncommon: brief burning or pricking on the treated areas of skin, drying and scaling of the treated skin, itching.

Rare: redness, contact dermatitis after application of Supraviran®, cream. In most cases allergy tests showed the other substances of the cream base to be the cause and not the active substance aciclovir. In contact dermatitis the above-mentioned side-effects occur more frequently and spread beyond the areas of skin treated with the cream.

Diseases of the immune system

Very rare: allergic reactions within a few minutes or hours (immediate allergic reactions) including swelling of the skin and mucous membranes (angioneurotic oedema).

If you notice any side-effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. HOW DO YOU STORE SUPRAVIRAN®, CREAM?

Keep medicines out of the reach and sight of children.

You must not use the medicine after the expiry date printed on the folding box and the tube.

Do not store above 25°C.

Date of Information

June 2005