

PATIENT INFORMATION LEAFLET

PENSIVIR 1% cream

For external use only.

- **Active substance(s):** Each 1 gram cream contains 10 mg penciclovir.
- **Excipient(s):** Cetomacrogol 1000, propylene glycol, cetostearyl alcohol, liquid paraffin, white paraffin and deionized water.

Read 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, please ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *If you go to a doctor or hospital during the use of this medicine, inform your doctor about this.*
- *Follow the instructions in this leaflet exactly. Do not use **higher or lower** doses than the dose which was recommended for you.*

What is in this leaflet:

- 1. What PENSIVIR is and what it is used for?***
- 2. What you need to know before you use PENSIVIR?***
- 3. How to use PENSIVIR?***
- 4. Possible side effects***
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1. What PENSIVIR is and what it is used for?

- PENSIVIR is a cream containing penciclovir as active substance. It has the appearance of a white or almost white cream
- PENSIVIR belongs to a group of drugs called topical antiviral agents, which contain drugs that prevent the proliferation of viruses
- PENSIVIR cream is presented in Al tubes of 2 g, 5 g and 10 g closed with HDPE closure in a box.
- PENSIVIR is used for the treatment of cold sore (Herpes labialis). This is a long-term inactivated virus; but when it triggers, it proliferates and cold sore occurs. Triggering may occur with colds, flu or exposure to strong sunlight. The virus can cause painful blisters filled with water in the lips. This medicine will help cold sore to heal more quickly and relieve your pain in a shorter time
- PENSIVIR stops the proliferation of viruses and helps to stop the transmission of cold sore in a shorter time, but it does not completely prevent the transmission of cold sore to other people

2. What you need to know before you use PENSIVIR?

Do not use PENSIVIR

If you have hypersensitivity to penciclovir, famciclovir or any of the other ingredients of PENSIVIR (see excipients list)

Use PENSIVIR with CAUTION

- If you are unsure that your sore is a cold sore
- If you are receiving treatment which weakens your immune system fighting against infections and if you have conditions such as HIV infection (AIDS), bone marrow transplant or cancer treatments
- Use the cream only on cold sores on your lips and around your mouth. Do not use the cream inside your mouth, nose or on your genital area. Avoid applying the cream into your eyes and near your eyes

What general precautions should you take when you have a cold sore?

Remember cold sores are infectious.

To prevent the virus infecting other parts of the body, or passing the virus to other people, it is important when you have a cold sore to:

- Avoid kissing, especially children
- Avoid oral sex
- Use only your own towel and do not share cutlery, cups, glasses, etc.
- Avoid breaking the blisters, as this may prolong the healing process
- Avoid touching your eyes, as the virus can cause a serious condition if it gets into the eyes
- Do not give this cream to other people, even if their symptoms are the same as yours

Please consult your doctor, even if these statements were applicable to you at any time in the past.

Pregnancy

Ask your doctor or pharmacist for advice before taking the medicine.

If you are pregnant, you can use it if your doctor has decided that it is absolutely necessary.

If you notice that you are pregnant during treatment, please consult your doctor or pharmacist immediately.

Breastfeeding

Ask your doctor or pharmacist for advice before taking the medicine.

If you are breastfeeding, do not use PENSIVIR unless your doctor requires it.

Driving and using machines

PENSIVIR has no effect on your ability to drive and use machines.

Important information about some of the ingredients of PENSIVIR

PENSIVIR contains propylene glycol and cetostearyl alcohol.

It contains cetostearyl alcohol which may cause local skin reactions (e.g. contact dermatitis)

It contains propylene glycol which may cause skin irritation.

Using with other medicines

There is no known interactions with other medicines.

Please tell your doctor or pharmacist if you are taking or have recently taken any other prescription or nonprescription medicine.

3. How to use PENSIVIR?

Instructions for use and dose/frequency of administration:

Unless recommended otherwise by your doctor, use at the indicated doses.

Check with your doctor or pharmacist if you are not sure.

Adults and children over 12 years:

Apply the cream every 2 hours during the day (about 8 times a day).

Continue treatment for 4 days. If the cold sore gets worse or does not improve after 4 days, talk to your doctor.

Start treatment at the earliest sign of a cold sore. However, you can use PENSIVIR even after the blister is formed.

- **Route and method of administration:**

PENSIVIR is for topical use.

Always wash your hands before and after applying the cream.

Squeeze a small amount onto your finger and apply to the affected area.

- **Different age groups:**

Use in children:

PENSIVIR is not recommended for the treatment of children under 12 years of age.

Use in elderly:

PENSIVIR can be used in the same dose recommended for adults in elderly.

- **Special conditions:**

Kidney/liver failure:

PENSIVIR has not studied in patients with renal or hepatic insufficiency.

If you have the impression that the effect of PENSIVIR is too strong or too weak, talk to your doctor or pharmacist.

If you have used more PENSIVIR than you should:

If you may have taken more PENSIVIR than you should, talk to a doctor or pharmacist.

There are unlikely to be any harmful effects if you have used a large amount of cream on your skin all at once, although some irritation of the skin may occur.

PENSIVIR is not harmful if accidentally swallowed and no treatment is necessary but it may cause irritation in the mouth. Please consult your doctor if you are concerned.

If you forget to use PENSIVIR:

Do not use a double dose to make up for a forgotten dose.

Apply the next application as soon as you remember and carry on as before.

If you stop using PENSIVIR:

When treatment is stopped, no effect other than the prolongation of the healing period of cold sores is expected.

4. Possible side effects?

Like all medicines, side effects can occur in people sensitive to the contents of PENSIVIR. PENSIVIR is generally well tolerated.

If any of the following occur stop using PENSIVIR and IMMEDIATELY inform your doctor or go to the nearest emergency department:

- Skin inflammations
- Redness and rash in skin
- Itching
- Blisters
- Edema

These are all very serious side effects. If you have any of them, this means you have serious allergy to PENSIVIR. You may need emergency medical care or hospitalization.

These very serious side effects occur very rarely.

If you notice any of the following, inform your doctor:

- Transient burning
- Stinging
- Numbness

These are mild effects of PENSIVIR.

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

5. How to store PENSIVIR?

Keep in the original package and out of the reach and sight of children.

Store at room temperature below 25°C.

Do not freeze.

Use in accordance with expiry date.

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

Do not use PENSIVIR if you notice any damage to the product and/or package or tube.

Marketing Authorization Holder:

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