

The PL includes alternative texts for different legal status in different countries as follows:

- [Boxed texts] are only applicable for OTC versions.

- [Grey-shaded texts in brackets] are only applicable for prescription versions.

For OTC use in Sweden, please refer to the approved Swedish package leaflet published on MPA's web site.

Package leaflet: Information for the user

Zovido 50 mg/g and 10 mg/g cream

Aciclovir and Hydrocortisone

[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.
- If you have any further questions, ask your doctor.
- 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. This includes any possible side effects not listed in this leaflet. See section 4.]

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if your symptoms persist 5 days after you have completed the treatment

<To be completed nationally>

What is in this leaflet:

1. What Zovido is and what it is used for
2. What you need to know before you use Zovido
3. How to use Zovido
4. Possible side effects
5. How to store Zovido
6. Contents of the pack and other information

1. What Zovido is and what it is used for

Zovido contains two active substances: aciclovir and hydrocortisone. Aciclovir is an antiviral that helps to fight the virus that causes cold sores. Hydrocortisone is a mild steroid that reduces the inflammation associated with a cold sore.

Zovido cream is used for the treatment of early signs and symptoms (e.g. tingling, itching or redness) of cold sores on the lips and skin close to the lips to reduce the chance of a cold sore progressing to a blister in adults and adolescents (12 years and older).

Even if your cold sore does develop into a blister, Zoviduo will shorten the healing process by approximately half to one day compared with the cream without the active substances.

A cold sore is caused by a virus called herpes simplex. The virus causes blisters and sores primarily on the lips but sometimes also in other areas on the face. A cold sore can develop when the body's immune system is weakened, for example when you have a cold or other infection. Stress, strong sunlight, cold temperatures or menstruation can also trigger a cold sore.

You must talk to a doctor if your symptoms persist 5 days after you have completed the treatment.

2. What you need to know before you use Zoviduo

Do not use Zoviduo

- if you are allergic to aciclovir, valaciclovir, hydrocortisone or any of the other ingredients of this medicine (listed in section 6).
- for any skin infections other than a cold sore.

Warnings and precautions

Only use Zoviduo on cold sores on your lips and skin close to the lips.

Talk to your doctor if you suffer with severe recurrent cold sores to check that you have no other underlying health issues.

Do not use Zoviduo:

- in the eye, inside your mouth or nose or on the genitals.
- to treat genital herpes.
- if your immune system is not working properly (e.g. if you have had a bone marrow transplant or if you have HIV) or if you have been diagnosed with weakened immune system.
- with any dressings such as a plaster or cold sore patch

Wash your hands before and after application to avoid making the cold sore worse or giving the infection to someone else.

Contact your doctor if you experience blurred vision or other visual disturbances.

Do not use for longer than 5 days.

Children

Do not give this medicine to children below 12 years of age, because it is not known if it works for them or if it is safe for them to use it.

Other medicines and Zoviduo

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines obtained without a prescription.

It is not known if the effect of Zoviduo can be affected by use of other medicines at the same time as Zoviduo.

Zoviduo with food and drink

Do not put the cream on just before eating since the cream may then be licked off.

Pregnancy, breast-feeding and fertility

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

This medicine should not be used during pregnancy or breast-feeding unless your doctor considers that the potential benefits outweigh the possibility of unknown risks.

Driving and using machines

Using Zoviduo does not affect your ability to drive and use machines.

Zoviduo contains propylene glycol and cetostearyl alcohol

Propylene glycol can cause skin irritation. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

Zoviduo contains sodium laurilsulfate

This medicine contains 8 mg sodium laurilsulfate in each 1g cream which is equivalent to 0.8% weight/weight.

Sodium laurilsulfate may cause local skin reactions (such as stinging or burning sensation) or increase skin reactions caused by other products when applied on the same area.

3. How to use Zoviduo

[Always use this medicine exactly as your doctor has told you. Check with your doctor if you are not sure]

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

For external use only

Do not use more than the recommended dose.

Adults and children 12 years and older

Apply the cream five times per day for 5 days (i.e. approximately every 3-4 hours whilst awake). It is recommended to start treatment as soon as possible preferably at the first sign or symptoms (e.g. tingling, redness or itching).

Do not use for longer than 5 days. You must talk to a doctor if your symptoms persist 5 days after you have completed the treatment.

Method of administration

Wash your hands before and after application to avoid making the cold sore worse or infecting someone else.

If you do develop an ulcer, do not touch the ulcer more than necessary in order not to spread the infection to other areas of the body, or to your eyes.

If you use more Zoviduo than you should

If you accidentally use too much or swallow the cream it is unlikely that any untoward effects would occur. However, if you swallow a large amount of the cream you should contact your doctor.

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

If you forget to use Zoviduo

If you miss a dose, apply when you remember and continue as before.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Stop using this medicine and contact your doctor immediately if you experience any of the following symptoms of an allergic reaction (very rare side effect: may affect up to 1 in 10,000 people):

- swelling of the face, tongue or throat, which may result in difficulty swallowing or breathing.
- hives.

The side effects below are listed by the likelihood with which they can occur:

Common: may affect up to 1 in 10 people:

- Drying or flaking of the skin.

Uncommon: may affect up to 1 in 100 people:

- Transient burning, tingling, or stinging may sometimes occur directly after application.
- Itching.

Rare: may affect up to 1 in 1,000 people:

- Redness of the skin.
- A change in skin colour.
- A localised rash or irritation of the skin with itching and burning feeling where the cream been applied.

Not known

- Blurred vision

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly [via the national reporting system listed in Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Zoviduo

Keep this medicine out of the sight and reach of children.

Store below 25°C. Do not refrigerate or freeze.

Do not use this medicine after the expiry date which is stated on the carton and tube after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the tube: 3 months.

Do not use this medicine if you notice that the cream has changed in appearance and/or texture.

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 to protect the environment.

6. Contents of the pack and other information

What Zoviduo contains

- The active substances are aciclovir and hydrocortisone. One gram cream contains 50 mg aciclovir and 10 mg hydrocortisone.
- The other ingredients are liquid paraffin, propylene glycol, isopropyl myristate, sodium laurilsulfate, cetostearyl alcohol, white soft paraffin, poloxamer 188, citric acid monohydrate, sodium hydroxide, hydrochloric acid and purified water.

What Zoviduo looks like and contents of the pack

Each tube contains 2 g of Zoviduo cream. Zoviduo is a white to yellowish cream.

The tube is made of polyethylene plastic aluminium laminate or aluminium.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

<To be completed nationally>

Manufacturer:

Glaxo Wellcome Operations
Harmire Road
Barnard Castle
County Durham
United Kingdom
DL12 8DT

GlaxoSmithKline Consumer Healthcare A/S,
Nykaer 68,
2605 Brøndby,
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Bahnhofbichi 13,
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This medicinal product is authorised in the Member States of the EEA under the following names:

Version

1.0

Approved

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Zovirax Duo: Belgium, Bulgaria, Croatia, Czech Republic, Estonia, Germany, Hungary, Ireland, Latvia, Luxembourg, Netherlands, Poland, Portugal, Romania, Slovakia
Zoviduo: Cyprus, Denmark, Greece, Iceland, Finland, Italy, Lithuania, Malta, Norway, Slovenia, Spain, Sweden
Activir Duo: Austria
Xerclear: France

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