

# PACKAGE LEAFLET: INFORMATION FOR THE USER

## Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Cymex Ultra carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve after 10 days.
- If any of the side effects get serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

## In this leaflet:

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

## 1. What Cymex Ultra is and what it is used for

Aciclovir belongs to a group of medicines called antivirals. Aciclovir works in cells that are infected by certain viruses, including the herpes simplex virus. It interferes with virus DNA, slowing down virus growth. Aciclovir is not harmful to human DNA.

## What is Cymex Ultra used for?

Cymex Ultra is used to treat cold sores of the lips and face caused by the herpes simplex virus. Aciclovir has been shown to speed up the healing of cold sore blisters if it is used soon enough.

## 2. Before you use Cymex Ultra

If you are not sure that your symptoms are caused by a cold sore then please consult your doctor or pharmacist before use.

## Do not use Cymex Ultra:

- If you are allergic to Aciclovir, valaciclovir, propylene glycol or any other ingredients of the preparation (see section 6 for a complete list of ingredients).
- Inside your mouth, to treat mouth ulcers and in the eyes or genital areas.

## Take special care with Cymex Ultra:

Tell your doctor or pharmacist before you start using the cream:

- If you have a weak immune system, for example after chemotherapy or radiotherapy or due to immune deficiency disease or following transplant surgery. Consult your doctor first if you have an infection.
- People with severe recurrent infection of the face and lips should contact their doctor or pharmacist.
- Cymex Ultra is not for use with eye infections.
- Cymex Ultra is not to be used to treat genital herpes.

## Taking other medicines:

Please tell your doctor or pharmacist if you are taking any of the following medicines:

- Probenecid used to prevent kidney problems associated with cidofovir.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines including medicines obtained without prescription.

## Pregnancy and Breastfeeding:

Tell your doctor if you are pregnant or planning to become pregnant. A small amount of this drug does pass into breast milk. If you are breast-feeding or are planning to breast-feed your baby tell your doctor.

## Driving and using machines:

This medicine should not affect your ability to drive or operate machinery.

## Important information about some of the ingredients of Cymex Ultra

Cymex Ultra contains cetyl alcohol and propylene glycol which may cause local skin reactions (skin irritation and redness).

## 3. How to use Cymex Ultra

### Cymex Ultra is for use on the skin only. It is not to be taken internally.

- To work at its best, Cymex Ultra should be started as soon as possible after the first symptoms of infection appear.
- People who suffer from cold sores can often tell when they are about to get a cold sore by a tingling or itching sensation. Cymex Ultra should be used at this tingling stage or just after skin blisters appear.

The following instructions will tell how to use Cymex Ultra-

1. Wash your hands.
2. Apply a thin film of Cymex Ultra to the infected skin, and the skin immediately next to it, using your fingertip. Take care not to rub the infected skin any more than you need to.
3. You should apply Cymex Ultra to the infected area 5 times each day, at intervals of about 4 hours, night time application can be omitted.
4. Wash your hands again. Herpes simplex is infectious and you should try to avoid touching the infected skin with your hands or with towels, etc. to prevent spreading the infection.

- Never apply Cymex Ultra to an area of the body called the mucous membranes, as the cream can cause irritation. These areas to avoid include the inside of the mouth and nose and the inside of the vagina.
- Treatment should be continued for at least 4 days. If the infection has not healed after this time, treatment can be continued for up to 5 days more.
- If your skin infection does not get better after 10 days of treatment or gets worse at any time tell your doctor as soon as possible.

#### **If you use more Cymex Ultra than you should:**

Cymex Ultra is not to be used in the mouth as it may irritate the skin in this area. If it is accidentally swallowed, do not worry, but contact your doctor or pharmacist for advice. Cymex Ultra should not be used in the eyes. If it gets in the eyes, wash it out with plenty of water. If your eye gets sore tell your doctor or pharmacist.

#### **If you forget to use Cymex Ultra:**

If you forget to use your cream, apply some as soon as you remember, then go on as before.

If you have any further questions on the use of Cymex Ultra ask your doctor or pharmacist.

#### **4. Possible side Effects**

Like all medicines Cymex Ultra can cause side effects, although not everybody gets them.

#### **Very rare (affecting less than 1 in 10000 users)**

An allergic (hypersensitive) reaction with symptoms such as swelling of the face, lips, tongue or throat, difficulty breathing, skin rash and itching. **Contact your doctor or hospital emergency department if you experience any of these symptoms.**

#### **Uncommon (affecting less than 1 in 100 users)**

- Mild drying or flaking of the skin.
- After application of the cream there may be some burning or stinging of the treated skin areas.
- Itching.

These may occur at the beginning of the treatment. If these signs do not get better after a few days then contact the doctor.

#### **Rare (affecting less than 1 in 1000 users)**

- Contact dermatitis with symptoms of a red rash or bumps, itching which may be severe with skin blistering, cracking and possibly bleeding.

In this case let your doctor know immediately. He will decide if you should continue with Cymex Ultra.

#### **Very rare (affecting less than 1 in 10000 users)**

- an allergic or hypersensitive reaction (see start of section).

#### **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 yellow card scheme at "<http://www.mhra.gov.uk/yellowcard>". By reporting side effects you can help provide more information on the safety of this medicine.

#### **5. How to store Cymex Ultra**

##### **Keep out of the sight and reach of children.**

Do not use Cymex Ultra after the expiry or 'use by' date shown on the container.

Use within 6 weeks of opening.

Keep Cymex Ultra in its original container and store at a temperature below 25°C but do not refrigerate or freeze.

#### **6. Further information**

##### **What the cream contains:**

The active ingredient is Aciclovir. Each gram of the cream contains 50mg of Aciclovir.

The other ingredients are stearyl macroglycerides, dimeticone, cetyl alcohol, liquid paraffin, white soft paraffin, propylene glycol and purified water.

##### **What Cymex Ultra looks like and contents of the pack**

Cymex Ultra is available from your pharmacist without prescription in a 2g tube.

##### **Marketing Authorisation Holder and Manufacturer**

Relonchem Limited, Cheshire House, Gorse Lane, Widnes, Cheshire, WA8 0RP, UK.

##### **Distributor**

Actavis, Barnstaple,