

## **Package leaflet: Information for the user**

### **Zovirax Duo 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.

#### **What is in this leaflet:**

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

#### **1. What Zovirax Duo is and what it is used for**

Zovirax Duo 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.

Zovirax Duo 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, Zovirax Duo 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 Zovirax Duo**

**Do not use Zovirax Duo**

- 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 Zovirax Duo 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 Zovirax Duo:

- 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 Zovirax Duo**

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 Zovirax Duo can be affected by use of other medicines at the same time as Zovirax Duo.

### **Zovirax Duo 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 Zovirax Duo does not affect your ability to drive and use machines.

### **Zovirax Duo contains propylene glycol and cetostearyl alcohol**

This medicine contains 200mg/g of propylene glycol. Cetostearyl alcohol may cause local skin reactions (e.g. contact dermatitis).

### **Zovirax Duo contains sodium laurilsulfate**

This medicine contains 8 mg/g of sodium laurilsulfate.

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 Zovirax Duo**

Always use this medicine exactly as your doctor has told you. Check with your doctor 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 Zovirax Duo 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 Zovirax Duo**

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 HPRA Pharmacovigilance, Website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Zovirax Duo**

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 Zovirax Duo 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 Zovirax Duo looks like and contents of the pack**

Each tube contains 2 g of Zovirax Duo cream. Zovirax Duo 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:**

Haleon Ireland Limited,  
12 Riverwalk, Citywest Business Campus, Dublin 24, Ireland

**Manufacturer:**

GlaxoSmithKline Consumer Healthcare ApS,  
Nykaer 68,  
2605 Brøndby,  
Denmark

Haleon Belgium NV,  
Da Vincilaan 5,  
1930 Zaventem,  
Belgium

Haleon-Gebro Consumer Health GmbH  
Bahnhofbichi 13,  
6391 Fieberbrunn  
Austria

**This medicinal product is authorised in the Member States of the EEA under the following names:**

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

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