

Reason for Update: Type 1AIN – Brexit CMC change – add an alternative batch release site. Note Poznan will be the active BR site for IE, and thus listed on printed artwork  
Market: Ireland  
Agency Approval Date: N/A as Type 1AIN  
Text Date: 19-Nov-2018  
Text Issue and Draft No.: Issue 3, Draft 1

## **(GSK logo)**

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

#### **Zovirax 5% w/w Cream aciclovir**

#### **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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

#### **Whats in this leaflet:**

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

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

Zovirax 5% w/w Cream (called 'Zovirax' in this leaflet) contains a medicine called aciclovir. This belongs to a group of medicines called antivirals. It is used to treat cold sores, genital herpes and other skin infections caused by the Herpes simplex virus. It works by stopping the growth of viruses that cause cold sores or genital herpes.

## **2 What you need to know before you use Zovirax**

#### **Do not use Zovirax if:**

- you are allergic to aciclovir, valaciclovir, propylene glycol or any of the other ingredients (listed in Section 6).

If you are not sure, talk to your doctor or pharmacist before using Zovirax.

#### **Warnings and precautions**

Talk to your doctor or pharmacist before using Zovirax:

- if you have a condition where your immune system works less well and your body is less able to fight infections (e.g. if you have HIV or AIDS or if you have had a bone marrow transplant).

Zovirax Cream is not for use in the mouth, eyes or the vagina.

If you are not sure, talk to your doctor or pharmacist before using Zovirax.

#### **Other medicines and Zovirax**

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

#### **Zovirax with food and drink**

Food and drink should not affect the absorption of your medicine.

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### **Pregnancy and breast-feeding**

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 taking this medicine

### **Driving and using machines**

Zovirax should not affect your ability to drive or use machines.

### **Zovirax contains cetosteraryl alcohol and propylene glycol**

Zovirax contains cetosteraryl alcohol; this may cause local skin reactions (e.g. contact dermatitis).

Zovirax also contains propylene glycol; this may cause skin irritation.

## **3 How to use Zovirax**

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

### **Applying the cream**

- Zovirax Cream is not for use in your mouth, eyes or the vagina. You should not mix Zovirax with anything before you use it, not even water.
- Always wash your hands before and after you use the cream.

### **Adults and children**

- Apply a thin layer of cream to the affected area five times a day. Zovirax cream should only be applied externally for the treatment of cold sores and genital herpes.
- You should space each application of Zovirax by four hours. Suggested times are: **7am, 11am, 3pm, 7pm and 11pm.**
- If your cold sore has not healed after 4 days, or your genital herpes sore has not healed after 5 days, you may use the cream for up to 10 days.
- If the affected area has still not healed after this, stop using the cream and tell your doctor.

### **If you use more Zovirax than you should**

Talk to your doctor or pharmacist if you use too much Zovirax. Zovirax Cream is for use on the skin, if you swallow any talk to your doctor or pharmacist.

### **If you forget to use Zovirax**

- If you forget to use Zovirax, use it as soon as you remember. However, if it is nearly time for your next application, skip the missed application.
- Do not use a double application to make up for a forgotten application.

## **4 Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

### **Allergic reactions** (may affect up to 1 in 10,000 people)

If you have an allergic reaction, **stop taking Zovirax and see a doctor straight away.** The signs may include:

- rash, itching or hives on your skin
- swelling of your face, lips, tongue or other parts of your body
- shortness of breath, wheezing or having trouble breathing
- unexplained fever and feeling faint, especially when standing up

Other side effects include:

### **Uncommon** (may affect up to 1 in 100 people)

- a burning or stinging feeling after applying the cream that goes away
- mild drying or flaking of your skin

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- itching

**Rare** (may affect up to 1 in 1,000 people)

- redness of your skin
- skin rash

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL – Dublin 2; Tel: +353 1 6764971; Fax +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

By reporting side effects you can help provide more information on the safety of this medicine.

## **5 How to store Zovirax**

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not store in a refrigerator.
- 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.
- Put the lid back on the tube after each time that you have used it
- 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 protect the environment.

## **6 Contents of the pack and other information**

### **What Zovirax 5% w/w Cream contains**

- The active substance is aciclovir.
- The cream contains 5% w/w aciclovir.
- The other ingredients are poloxamer 407, cetostearyl alcohol, sodium laurilsulfate, white soft paraffin, liquid paraffin, propylene glycol, purified water, arlacel 165 (glycerol monostearate and macrogol stearate), dimeticone 20.

### **What Zovirax looks like and contents of the pack**

Each carton contains a 2 g or 10 g tube of Zovirax. The tube has a screw cap and contains a smooth, white to off-white cream.

### **Marketing authorisation holder and manufacturer**

#### **Marketing authorisation holder**

GlaxoSmithKline (Ireland) Ltd, 12 Riverwalk, Citywest Business Campus, Dublin 24

#### **Manufacturer**

Glaxo Operations UK Ltd, Barnard Castle, Durham, DL12 8DT, UK

Or

GlaxoSmithKline Pharmaceuticals S.A.,  
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60-322 Poznan,  
Poland.

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