

## Package leaflet: Information for the user

### Zovirax Double Strength 400 mg/5 mL Oral Suspension aciclovir

**Read all of this leaflet carefully before you start taking 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. Do not pass it on to others. It may harm them, even if their symptoms 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.

#### What is in this leaflet:

- 1 What Zovirax is and what it is used for
- 2 What you need to know before you take Zovirax
- 3 How to take 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 Double Strength 400 mg/5 mL Oral Suspension (called 'Zovirax' in this leaflet) contains the active substance aciclovir. This belongs to a group of medicines called antivirals. It works by stopping the growth of certain viruses.

Zovirax Double Strength 400 mg/5 mL Oral Suspension can be used to:

- treat herpes simplex virus infections of the skin and mucous membranes (cold sores, genital herpes and other herpes simplex infections)
- prevent recurrences of recurrent herpes simplex infections (stop these problems returning after you have had them)
- prevent herpes simplex infections in immunocompromised patients (stop these problems in people whose immune systems work less well, which means their bodies are less able to fight infections)
- treat chickenpox and shingles

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

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

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

Do not take Zovirax if the above applies to you. If you are not sure, check with your doctor or pharmacist before taking Zovirax.

##### **Warnings and precautions**

Check with your doctor or pharmacist before taking Zovirax if:

- you have kidney problems
- you are over 65 years of age.
- you are thirsty. You must make sure you drink plenty of liquids such as water whilst taking this medicine
- your immune system is weak

If you are not sure if the above apply to you, check with your doctor or pharmacist before taking Zovirax.

##### **Children**

There is no data available to support the use of this medicine in stopping cold sores and genital herpes returning after having had them and treatment of shingles in children whose immune systems work well.

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

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

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

- probenecid, used to treat gout
- cimetidine, used to treat stomach ulcers
- mycophenolate mofetil, used to stop your body rejecting transplanted organs.

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

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

### **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 taking this medicine

The ingredients in Zovirax can pass into breast milk. If you are breast-feeding, you must check with your doctor before you take Zovirax.

### **Driving and using machines**

Some side effects such as feeling drowsy or sleepy may impair your ability to concentrate and react. Make sure you are not affected before you drive or operate machinery

### **Zovirax contains**

**Methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216)** which may cause allergic reactions (possibly delayed).

**Liquid Sorbitol solution (non-crystallising) (E420);** this medicine contains 2.25 g Liquid Sorbitol solution (non-crystallising) (E420) per 5 mL. Sorbitol is a source of fructose. If your doctor has told you that you (or your child) have an intolerance to some sugars or if you have been diagnosed with hereditary fructose intolerance (HFI), a rare genetic disorder in which a person cannot break down fructose, talk to your doctor before you (or your child) take or receive this medicine. Sorbitol may cause gastrointestinal discomfort and mild laxative effect.

**Benzyl alcohol;** this medicine contains less than 1 mg benzyl alcohol per 5 mL of oral solution. Benzyl alcohol may cause allergic reactions. Benzyl alcohol has been linked with the risk of severe side effects including breathing problems (called "gasping syndrome") in young children. Do not give to your newborn baby (up to 4 weeks old), unless recommended by your doctor. Do not use for more than a week in young children (less than 3 years old), unless advised by your doctor or pharmacist.

Ask your doctor or pharmacist for advice if you are pregnant or breast-feeding. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis"). Ask your doctor or pharmacist for advice if you have a liver or kidney disease. This is because large amounts of benzyl alcohol can build-up in your body and may cause side effects (called "metabolic acidosis").

## **3 How to take Zovirax**

Your doctor will decide on the correct dose to take, how often and for how long, depending on:

- your age
- the type of infection you have
- whether it is to treat the infection or to stop it coming back

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

### **Taking this medicine**

- Take this medicine by mouth.
- Use the spoon provided to carefully measure the dose needed.
- Start to take Zovirax as soon as possible.
- Drink plenty of liquids such as water while taking this medicine.

The dose that you should take will depend on what you have been given Zovirax for. Your doctor will discuss this with you.

**Treatment of herpes simplex infections (treatment of cold sores, genital herpes and other herpes simplex infections):**

**Use in adults**

The recommended dose is 200 mg (400 mg/5 ml oral suspension: 2.5 ml), five times daily, during the waking part of the day, approximately every four hours for five days.

Your doctor can adjust the doses as required (e.g. in case you have reduced immune resistance; you are elderly or you have kidney problems). If you are elderly or have kidney problems, it is important to drink plenty of water during treatment.

**Use in children**

Children under 2 years of age: 100 mg (400 mg/5 ml oral suspension: 1.25 ml), five times daily, during the waking part of the day, every four hours.

Children over 2 years of age: 200 mg (400 mg/5 ml oral suspension: 2.5 ml), five times daily, during the waking part of the day, every four hours.

**Do not dilute the oral suspension.** To administer the prescribed dose, use the measuring device provided with the package or a measuring device suggested by your doctor or pharmacist.

**Prevent recurrences of recurrent herpes simplex infections (stopping these problems returning after you have had them):**

**Use in adults**

The recommended dose is 200 mg (400 mg/5 ml oral suspension: 2.5 ml), four times daily, every six hours.

You should take Zovirax until your doctor tells you to stop.

Your doctor can adjust the doses as required (e.g. in case you have reduced immune resistance; you are elderly or you have kidney problems). If you are elderly or have kidney problems, it is important to drink plenty of water during treatment.

**Prevent herpes simplex infections in immunocompromised patients (stopping these problems in people whose immune systems work less well, which means their bodies are less able to fight infections):**

**Use in adults**

The recommended dose is 200 mg (400 mg/5 ml oral suspension: 2.5 ml), four times daily, every six hours.

You should take Zovirax until your doctor tells you to stop.

Your doctor can adjust the doses as required (e.g. in case you have reduced immune resistance; you are elderly or you have kidney problems). If you are elderly or have kidney problems, it is important to drink plenty of water during treatment.

**Use in children**

Children under 2 years of age: 100 mg (400 mg/5 ml oral suspension: 1.25 ml), four times daily, every six hours.

Children over 2 years of age: 200 mg (400 mg/5 ml oral suspension: 2.5 ml), four times daily, every six hours.

**Do not dilute the oral suspension.** To administer the prescribed dose, use the measuring device provided with the package or a measuring device suggested by your doctor or pharmacist.

**Treatment of chickenpox and shingles:**

**Use in adults**

The recommended dose is 800 mg (400 mg/5 ml oral suspension: 10 ml) taken five times daily, during the waking part of the day, approximately every four hours for seven days.

Your doctor can adjust the doses as required (e.g. in case you have reduced immune resistance; you are elderly or you have kidney problems). If you are elderly or have kidney problems, it is important to drink plenty of water during treatment.

#### **Use in children**

Children under 2 years of age: 200 mg (400 mg/5 ml oral suspension: 2.5 ml), four times daily.

Children 2 to 6 years of age: 400 mg (400 mg/5 ml oral suspension: 5 ml), four times daily.

Children over 6 years of age: 800 mg (400 mg/5 ml oral suspension: 10 ml), four times daily.

The treatment should be followed for five days. Your doctor can consider dose adjustment according to the body weight.

To administer the prescribed dose, use the measuring device provided with the package or a measuring device suggested by your doctor or pharmacist.

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

Zovirax is not usually harmful, unless you take too much over several days. Talk to your doctor or pharmacist if you take too much Zovirax. Take the medicine pack with you.

#### **If you forget to take Zovirax**

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

### **4 Possible side effects**

Like all medicines, Zovirax 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 1,000 people)

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

- bumpy rash, itching or hives on your skin
- swelling of your face, lips, tongue or other parts of your body (angioedema)
- shortness of breath, wheezing or trouble breathing
- unexplained fever (high temperature) and feeling faint, especially when standing up.

Other side effects include:

#### **Common** (may affect up to 1 in 10 people)

- headache
- feeling dizzy
- feeling or being sick
- diarrhoea
- stomach pains
- skin reaction after exposure to light (photosensitivity)
- itching
- feeling tired (fatigue)
- fever

#### **Uncommon** (affects less than 1 in 100 people)

- bumpy, itchy, hive-like rash (urticaria)
- hair loss

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

- difficulty breathing
- effects on some blood and urine tests including changes in the levels of liver enzymes and blood count changes
- swelling of your face, lips, mouth, tongue or throat (angioedema).

#### **Very rare** (may affect up to 1 in 10,000 people)

- nosebleeds and bruising more easily than usual as a result of reduced numbers in blood platelets (thrombocytopenia)

- feeling agitated or confused
- shaking or tremors
- hallucinations (seeing or hearing things that aren't there)
- fits (seizures)
- feeling unusually sleepy or drowsy
- unsteadiness when walking and lack of coordination (ataxia)
- difficulty speaking or hoarseness (dysarthria)
- inability to think or judge clearly or concentrate
- unconsciousness (coma)
- disturbances of behaviour, speech and bodily movements
- damage or malfunction of the brain (encephalopathy) which is evident by an altered mental state
- inflammation of the liver (hepatitis)
- yellowing of your skin and whites of your eyes (jaundice)
- kidney problems where you pass little or no urine
- pain in your lower back, the kidney area of your back or just above your hip (renal pain).
- fatigue, decreased energy, weakness, shortness of breath, light-headedness, palpitations, looking pale (anaemia)

#### **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**

- Keep out of the sight and reach of children.
- Do not store above 25°C.
- Do not use Zovirax after the expiry date which is stated on the carton. The expiry date (Exp.) refers to the last day of that month.
- 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 Double Strength 400 mg/5 mL Oral Suspension contains**

- The active substance is aciclovir.
- The other ingredients are liquid sorbitol solution non-crystallising [E420], glycerol, dispersible cellulose, methyl parahydroxybenzoate [E218], propyl parahydroxybenzoate [E216], orange flavour (contains benzyl alcohol) and purified water.

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

Zovirax Double Strength 400 mg/5 mL Oral Suspension is supplied to you in an amber-coloured glass bottle, containing of 100 mL of an off-white suspension. The medicine comes with a double-ended measuring spoon. One end of the spoon will give you 5 mL of the suspension and the other will give you 2.5 mL. The 2.5 mL spoon contains a 1.25 mL graduation mark.

Each 5 mL of Zovirax Double Strength 400 mg/5 mL Oral Suspension contains 400 mg aciclovir.

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

##### **Marketing authorisation holder**

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

##### **Manufacturer**

Aspen Bad Oldesloe GmbH, Industriestrasse 32-36, 23843 Bad Oldesloe, Germany

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