

## OZVIR

Aciclovir 200 mg Tablets

### Consumer Medicine Information

#### What is in this leaflet

This leaflet answers some common questions about **OZVIR** (aciclovir).

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking this medicine against the benefits it is expected to have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

Keep this leaflet with this medicine. You may need to read it again.

#### What OZVIR is used for

**OZVIR** contains aciclovir, a compound that belongs to a group of medicines called antivirals.

**OZVIR** is used for the treatment of shingles (herpes zoster), impaired immunity and genital herpes.

In the case of shingles, **OZVIR** works by stopping the multiplication of the virus which causes shingles. It can reduce the length and severity of an outbreak of shingles but it will not get rid of the virus from your body.

Aciclovir at high strength is used as part of the management program in people who have human immunodeficiency virus disease (HIV). It acts by preventing further damage to the immune system. In these people, **OZVIR** also guards against the herpes virus disease.

Aciclovir does not get rid of the virus from your body.

Your doctor may have prescribed **OZVIR** for another purpose.

**OZVIR** is not recommended for use in children as there have been no studies of its effects in children.

**Ask your doctor if you have any questions about why OZVIR has been prescribed for you.**

This medicine is only available with a doctor's prescription.

#### Before you take OZVIR

##### When you must not take it

##### Do not take OZVIR if:

- you have ever had an allergic reaction to **OZVIR** or to any of the ingredients listed at the end of this leaflet.  
Some of the symptoms of an allergic reaction may include a skin rash similar to hives, itchiness, shortness of breath, swelling of the face, lips or tongue.

**If you are not sure whether you should be taking OZVIR, talk to your doctor.**

##### Do not take OZVIR if:

- the packaging shows signs of tampering or does not look quite right.
- the expiry date marked on the packaging has passed, even though the tablets may look alright. If it has expired or is damaged, return it to your pharmacist for disposal.

##### Before you start to take it

##### Tell your doctor if:

- you are pregnant or intend to become pregnant while taking **OZVIR**.  
Medicines like **OZVIR** may affect the developing baby if you take it during pregnancy. Your doctor will discuss the possible risks and benefits of taking **OZVIR** during pregnancy.
- you are breast-feeding or wish to breast-feed.  
Your doctor will discuss the risks and benefits of taking **OZVIR** when breast-feeding.
- you are allergic to any foods, dyes, preservatives or any other medicines.
- you have any health problems, including:
  - kidney or liver problems
  - neurological problems
  - receiving interferon or methotrexate treatment
  - insufficient oxygen level in blood or tissue, or altitude sicknessSymptoms are dizziness, shortness of breath, and mental confusion

##### Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop. Some medicines and **OZVIR** may interfere with each other.

Your doctor or pharmacist has a complete list of medicines to be careful with or avoid while taking **OZVIR**.

**If you have not told your doctor or pharmacist about these things, tell them before you start taking OZVIR.**

#### How OZVIR is given

##### How to take it

Take **OZVIR** exactly as your doctor has prescribed.

Follow all directions given to you by your doctor or pharmacist. They may differ from the information contained in this leaflet.

##### How much to take

##### Treatment for Shingles

The normal dose is to take 800 mg five times a day approximately every 4 hours throughout the day while awake, for 7 days. Either take your tablets at 7am, 11am, 3 pm, 7pm and 11pm or note down the times that suit your daily schedule.

##### Management of advanced HIV

The dose is 800 mg four times a day every 6 hours, for as long as your doctor tells you.

##### Treatment of initial genital herpes

One 200 mg tablet every four hours while awake, for a total of 5 tablets daily, for 10 days.

##### Intermittent therapy for recurrent genital herpes

One 200 mg tablet every four hours while awake, for a total of 5 tablets daily, for 5 days. Therapy should be initiated at the earliest sign or symptom (prodrome) of recurrence.

##### Chronic suppressive therapy for recurrent genital herpes

One 200 mg tablet three times a day for up to 6 months. For most people, one 200 mg tablet twice a day gives satisfactory results.

The Pharmacist's label on the pack will give the dosage instructions for your treatment.

**OZVIR** tablets may be dispersed in a glass of water prior to being taken or alternatively swallow the tablets whole with a glass of water. You should drink plenty of fluids.

**If you do not understand the instructions on the box ask your doctor or pharmacist for help.**

##### How long to take it

You must take **OZVIR** for as long as your doctor tells you. Do not stop taking **OZVIR** just because you feel better.

##### If you forget to take it

If you forget to take a dose, take one as soon as you remember, unless this is within an hour of when the next dose is due. Then go on as before.

Do not take a double dose to make up for the dose that you missed. This may increase the chance of getting an unwanted side effect.

##### If you take too much (overdose)

**Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to accident and emergency (Casualty) at your nearest hospital if you think you or anyone else may have taken too much OZVIR. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Keep telephone numbers of these places/services handy.**

#### While you are using OZVIR

##### Things you must do

**Take OZVIR tablets exactly as your doctor tells you to.**

Visit your doctor regularly for check-ups.

Tell any other doctors, dentists and pharmacists who are treating you that you are taking **OZVIR**

If you are about to start any new medicine, tell your doctor or pharmacist that you are taking **OZVIR**

If you become pregnant while taking **OZVIR** tell your doctor immediately.

##### Things you must not do

**Do not take OZVIR to treat any other conditions unless your doctor says to.**

**Do not give this medicine to anyone else, even if they have the same condition as you.**

**Do not stop taking your medicine or lower the dosage without checking with your doctor.**

##### Things to be careful of

Be careful driving or operating machinery until you know how **OZVIR** affects you. **OZVIR** may cause dizziness or drowsiness in some people and affect alertness.

If this occurs, do not drive, operate machinery or do things that could be dangerous if you are not alert.

#### Side effects

**Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking OZVIR.**

**OZVIR** helps most people but it may have some unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the list of possible side effects. You may not experience any of them.

**Tell your doctor if you experience any of the following and they worry you:**

- Nausea
- Vomiting
- Headache

These are the more common side effects of **OZVIR**.

**Tell your doctor if you experience any of the following:**

- Dizziness, fatigue, fast heart rate, fever, chills, short of breath
- Confusion, sleep disturbances, hallucinations, shakiness, irritability
- Weight loss, fluid retention, pain in the leg and joints, vein disorders
- Diarrhoea, constipation
- Sore throat, taste disturbances, swollen glands
- Skin rashes, hair loss
- Cramps, menstrual problems
- Disorders of the eyes and liver

**These may or may not be due to OZVIR but you should tell your doctor if they worry you.**

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

**If you notice any other symptoms that worry you, check with your doctor.**

Ask your doctor or pharmacist if you don't understand anything in this list.

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## After using it

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### *Storage*

Keep **OZVIR** where children cannot reach it.

Keep your tablets in the pack until it is time to take them. If you take your tablets out of the pack they may not keep as well.

Keep your tablets in a cool dry place where temperatures stay below 25°C. Protect from light.

Do not store **OZVIR** or any other medicine in the bathroom or near a sink.

Do not leave your medicines on a window sill or in the car. Heat and dampness can destroy some medicines.

### *Disposal*

If your doctor tells you to stop taking **OZVIR**, or the tablets have passed their expiry date, ask your pharmacist what to do with any left over.

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## Product description

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### *What it looks like*

**OZVIR** tablets are capsule-shaped, biconvex, uncoated, white to off-white tablets with 200 embossed on one side and ACV on the other side. Available in blister packs of 90 tablets.

### *Ingredients*

#### **Active ingredient:**

Aciclovir

#### **Inactive ingredients:**

Microcrystalline cellulose, sodium starch glycolate, starch-pregelatinised maize, silica-colloidal anhydrous and magnesium stearate.

### *Australian Registration Numbers*

**OZVIR** 200 mg tablets blister pack: AUST R 117380

## *Sponsor*

**OZVIR** tablets are supplied in Australia by:

**Ranbaxy Australia Pty. Ltd**

Suite 4.02, Building D, Level 4

12-24 Talavera Road

North Ryde, NSW 2113

Australia

This leaflet was prepared in Mar 2011.