

# ACICLOVIR VIATRIS

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using ACICLOVIR VIATRIS?

ACICLOVIR VIATRIS contains the active ingredient aciclovir sodium dihydrate. ACICLOVIR VIATRIS is an antiviral medicine, used for the management of certain infections caused by viruses, such as herpes and shingles.

For more information, see Section [1. Why am I using ACICLOVIR VIATRIS?](#) in the full CMI.

### 2. What should I know before I use ACICLOVIR VIATRIS?

Do not use if you have ever had an allergic reaction to aciclovir, valaciclovir, or any of the ingredients listed at the end of the CMI.

**Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.**

For more information, see Section [2. What should I know before I use ACICLOVIR VIATRIS?](#) in the full CMI.

### **3. What if I am taking other medicines?**

Some medicines may interfere with ACICLOVIR VIATRIS and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

### **4. How do I use ACICLOVIR VIATRIS?**

- ACICLOVIR VIATRIS is given by slow infusion directly into the bloodstream. It is administered by a doctor or nurse.
- Your doctor will decide what dose you will receive. The amount you will be given will be specific to your age, weight, general health and underlying conditions.

More instructions can be found in Section [4. How do I use ACICLOVIR VIATRIS?](#) in the full CMI.

## 5. What should I know while using ACICLOVIR VIATRIS?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Drink plenty of fluids as instructed by your doctor or nurse. If you cannot drink due to your condition, your doctor will ensure that you receive plenty of fluids.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not use if you have ever had an allergic reaction to aciclovir, valaciclovir, or any of the ingredients listed at the end of the CMI.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful before you drive or use any machines or tools until you know how ACICLOVIR VIATRIS affects you.</li><li>• ACICLOVIR VIATRIS may cause headache, dizziness, ataxia, encephalopathy, somnolence, confusion, tremor, hallucination, psychosis, convulsion</li></ul>

	and coma in some people.
<b>Drinking alcohol</b>	<ul style="list-style-type: none"> <li>• Be careful when drinking alcohol while you are taking this medicine.</li> <li>• If you drink alcohol, symptoms such as headache or dizziness may be worse.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• ACICLOVIR VIATRIS will be stored in the pharmacy or on the ward.</li> <li>• Stored in a cool dry place where the temperature stays below 25°C. Protect from moisture.</li> </ul>

For more information, see Section [5. What should I know while using ACICLOVIR VIATRIS?](#) in the full CMI.

## 6. Are there any side effects?

**Tell your doctor or nurse if you have any of these less serious side effects and they worry you:** discomfort, swelling, redness or heat at the injection site; nausea and/or vomiting; loss of appetite. **Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects:** difficulty

breathing; swelling of the face, lips, tongue or other parts of the body (allergic reaction); abdominal pain; diarrhoea or bloody diarrhoea; abnormal bleeding or bruising; blood in urine or dark urine; seizures; tremors; confusion; delusion; loss of coordination; difficulty in speech; yellowing of the skin or eyes; fever. **This is not a complete list of all possible side effects.** For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

# ACICLOVIR VIATRIS

**Active ingredient(s):** *aciclovir sodium dihydrate*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using ACICLOVIR VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using ACICLOVIR VIATRIS.**

**Where to find information in this leaflet:**

- [1. Why am I using ACICLOVIR VIATRIS?](#)
- [2. What should I know before I use ACICLOVIR VIATRIS?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use ACICLOVIR VIATRIS?](#)
- [5. What should I know while using ACICLOVIR VIATRIS?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## 1. Why am I using ACICLOVIR VIATRIS?

**ACICLOVIR VIATRIS contains the active ingredient aciclovir sodium dihydrate.** ACICLOVIR VIATRIS belongs to a group of medicines called antivirals.

**ACICLOVIR VIATRIS is used for the management of certain infections caused by viruses, such as shingles and herpes.**

It works by preventing the multiplication of the virus which is causing the condition.

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

ACICLOVIR VIATRIS is not addictive.

## **2. What should I know before I use ACICLOVIR VIATRIS?**

### **Warnings**

#### **Do not use ACICLOVIR VIATRIS if:**

- you are allergic to aciclovir, valaciclovir, or any of the other ingredients listed at the end of this leaflet. Some of the symptoms of an allergic reaction may include:
  - asthma
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips tongue or other parts of the body
  - rash, itching or hives on the skin

Always check the ingredients to make sure you can use this medicine.

**Do not give ACICLOVIR VIATRIS to a child under the age of one years.**

Safety and effectiveness of ACICLOVIR VIATRIS in children younger than one years have not been established.

If you are not sure whether you should start taking this medicine, talk to your doctor.

### **Check with your doctor if you:**

- are allergic to any other medicines, foods, preservatives or dyes.
- have had any other health problems including:
  - any condition affecting your nervous system
  - hypoxia (inadequate oxygen supply to the cells of the body)
  - liver or kidney problems
  - irregular electrolyte levels
  - dehydration
  - low blood pressure
- take any medicines for any other condition.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

### **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Like most medicines, ACICLOVIR VIATRIS is not recommended for use during pregnancy. Your doctor can discuss with you the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

ACICLOVIR VIATRIS passes into breast milk and therefore there is a possibility that the breast-fed baby may be affected. It is not recommended for use while breast-feeding. Your doctor will discuss the risk and benefits of using ACICLOVIR VIATRIS when breastfeeding.

**If you have not told your doctor about any of the above, tell them before you start ACICLOVIR VIATRIS.**

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

**Some medicines may interfere with ACICLOVIR VIATRIS. These include:**

- probenecid, a medicine used to treat gout
- cimetidine, a medicine used for stomach ulcers
- mycophenolate, ciclosporin, tacrolimus or interferon, medicines used to control the immune system
- diuretics, that is, medicines to prevent fluid retention
- zidovudine, a medicine used for HIV infection or AIDS

- methotrexate, a medicine used for cancer and conditions of the immune system
- lithium, a medicine used for treatment of mental illness
- theophylline, a medicine used to treat lung diseases.

These medicines may be affected by ACICLOVIR VIATRIS or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines. Your doctor or pharmacist can tell you what to do if you are using any of these medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ACICLOVIR VIATRIS.**

## **4. How is ACICLOVIR VIATRIS given?**

### **How is it given and how much**

- ACICLOVIR VIATRIS is given by slow infusion directly into the bloodstream. It is administered by a doctor or nurse.
- Your doctor will decide what dose you will receive. The amount you will be given will be specific to your age, weight, general health and underlying conditions.
- The duration of treatment is dependent on the condition that is being treated.

## **If you take too much ACICLOVIR VIATRIS**

If you think that you or anyone else may have used too much ACICLOVIR VIATRIS, urgent medical attention may be needed.

### **You should immediately:**

- phone the Poisons Information Centre (Australia telephone 13 11 26) for advice, or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

### **You should do this even if there are no signs of discomfort or poisoning.**

You may need urgent medical attention.

Your prescribing doctor has information on how to recognise and treat an overdose.

Symptoms of an overdose may include nausea, vomiting, stomach pain, confusion, agitation, drowsiness, hallucinations, tremors or convulsions.

You will be closely monitored whilst you are being treated with this medicine. Should any symptoms of an overdose occur your doctor would manage them.

## **5. What should I know while using ACICLOVIR VIATRIS?**

### **Things you should do**

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using ACICLOVIR VIATRIS.
- Remind any doctor, dentist or pharmacist you visit that you are using ACICLOVIR VIATRIS.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are using ACICLOVIR VIATRIS. It may affect other medicines used during surgery.
- If you are about to have any blood tests, tell your doctor that you are taking this medicine. It may interfere with the results of some tests.
- If the symptoms of your illness do not improve within a few days, or if they become worse, tell your doctor or nurse.
- Drink plenty of fluids as instructed by your doctor or nurse. If you cannot drink due to your condition, your doctor will ensure that you receive plenty of fluids.
- Keep all of your doctor's appointments so that your progress can be checked.

### **Call your doctor straight away if you:**

- become pregnant while taking this medicine.

## **Driving or using machines**

**Be careful before you drive or use any machines or tools until you know how ACICLOVIR VIATRIS affects you.**

ACICLOVIR VIATRIS may cause headache, dizziness, ataxia, encephalopathy, somnolence, confusion, tremor, hallucination, psychosis, convulsion and coma in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

## **Drinking alcohol**

**Tell your doctor if you drink alcohol.**

**Be careful when drinking alcohol while you are taking this medicine.**

If you drink alcohol, symptoms such as headache or dizziness may be worse.

## **Things you must not do**

**If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly.**

Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

## Looking after your medicine

- ACICLOVIR VIATRIS will be stored in the pharmacy or on the ward.
- Stored in a cool dry place where the temperature stays below 25°C.
- Protect from moisture.

Follow the instructions in the carton on how to take care of your medicine properly.

## Getting rid of any unwanted medicine

ACICLOVIR VIATRIS is intended for single patient use only. Any remaining content should be discarded.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

**Tell your doctor, nurse or pharmacist as soon as possible if you do not feel well while you are using ACICLOVIR VIATRIS.**

This medicine helps most people with viral infection caused by shingles and herpes, but it may have unwanted side effects in some people.

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

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

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

If you are over 65 years of age you may have an increased chance of getting side effects.

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<p><b>Injection site reactions:</b></p> <ul style="list-style-type: none"><li>• discomfort, swelling, redness or heat at the injection site</li></ul> <p><b>Gastrointestinal reactions:</b></p> <ul style="list-style-type: none"><li>• nausea and/or vomiting</li><li>• loss of appetite</li></ul>	<p><b>Tell your doctor or nurse if you have any of these less serious side effects and they worry you.</b></p>

### **Serious side effects**

<b>Serious side effects</b>	<b>What to do</b>
<p><b>Allergic reaction symptoms:</b></p> <ul style="list-style-type: none"><li>• wheezing, shortness of breath or difficulty breathing</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● swelling of the face, lips, tongue or other parts of the body</li> <li>● rash, sores, itching, ulcers or hives on the skin</li> </ul> <p><b>Bleeding and related side effects:</b></p> <ul style="list-style-type: none"> <li>● abnormal bleeding or bruising</li> <li>● severe blisters and bleeding in the lips, eyes, mouth and genitals</li> </ul> <p><b>Gastrointestinal related symptoms:</b></p> <ul style="list-style-type: none"> <li>● pain or problems in passing urine</li> <li>● blood in urine or dark urine</li> <li>● diarrhoea, bloody diarrhoea</li> <li>● abdominal pain</li> </ul> <p><b>Liver related symptoms:</b></p> <ul style="list-style-type: none"> <li>● jaundice or hepatitis</li> </ul> <p><b>Psychological related symptoms:</b></p>	<p><b>notice any of these serious side effects.</b></p>

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● seizures (fits)</li> <li>● confusion, agitation or reduced ability to concentrate</li> <li>● feeling sad or changes in thinking</li> <li>● tremor</li> <li>● hallucinations or delusions</li> <li>● dizziness</li> <li>● loss of coordination, or voluntary muscle movements</li> <li>● pins and needles sensation on skin</li> <li>● difficulty in speech</li> </ul> <p><b>Injection site reactions:</b></p> <ul style="list-style-type: none"> <li>● sudden pain or inflammatory reaction at the injection site</li> </ul> <p><b>Skin and eye reactions:</b></p> <ul style="list-style-type: none"> <li>● yellowing of the skin and eyes</li> <li>● itching</li> <li>● purplish spots or patches</li> </ul> <p><b>General:</b></p>	

<b>Serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>● feeling generally unwell</li> <li>● looking pale</li> <li>● fever</li> <li>● tiredness</li> <li>● headaches</li> <li>● being short of breath when exercising</li> </ul>	

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.** Your doctor may request blood test in order to monitor your progress, some side effects can only be detected by blood testing.

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## 7. Product details

This medicine is only available with a doctor's prescription. It should only be given to you under the supervision of medical professionals.

### What ACICLOVIR VIATRIS contains

<b>Active ingredient (main ingredient)</b>	Aciclovir sodium dihydrate 250 mg or 500 mg each vial
<b>Other ingredients (inactive ingredients)</b>	N/A
<b>Potential allergens</b>	N/A

**Do not take this medicine if you are allergic to any of these ingredients.**

### What ACICLOVIR VIATRIS looks like

ACICLOVIR VIATRIS 250 mg is supplied in colourless glass vial containing white to off white lyophilized powder or cake (AUST R 233649).

ACICLOVIR VIATRIS 500 mg is supplied in colourless glass vial containing white to off white lyophilized powder or cake (AUST R 233648).

Available in packs of 5 vials.

## **Who distributes ACICLOVIR VIATRIS**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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