

# Valaciclovir RBX

## 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.

### 1. Why am I using Valaciclovir RBX?

Valaciclovir RBX contains the active ingredient valaciclovir hydrochloride. Valaciclovir RBX tablets belong to a group of medicines called antivirals. They are used for the treatment of genital herpes, herpes zoster (shingles) and ophthalmic zoster (shingles affecting the eye region)

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

### 2. What should I know before I use Valaciclovir RBX?

Do not use if you have ever had an allergic reaction to Valaciclovir hydrochloride 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 Valaciclovir RBX?](#) in the full CMI.

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

Some medicines may interfere with Valaciclovir RBX medicine name 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 Valaciclovir RBX?

- Your doctor will tell you how many tablets, how many doses and when to take your doses each day.
- Swallow the tablets whole with a glass of water and take Valaciclovir RBX at about the same time each day.

More instructions can be found in Section [4. How do I use Valaciclovir RBX medicine name?](#) in the full CMI.

### 5. What should I know while using Valaciclovir RBX?

<b>Things you should do</b>	<ul style="list-style-type: none"><li>• Remind any doctor, dentist, pharmacist or other healthcare professionals you visit that you are using Valaciclovir RBX.</li><li>• If you become pregnant, or are trying to become pregnant, or intend to breastfeed while taking this medicine, tell your doctor immediately.</li><li>• Drink plenty of fluids while you are taking Valaciclovir RBX tablets.</li></ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"><li>• Do not stop using this medicine suddenly, or change the dose, without first checking with your doctor.</li><li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li></ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"><li>• Be careful driving or operating machinery until you know how Valaciclovir RBX affects you.</li></ul>
<b>Drinking alcohol</b>	<ul style="list-style-type: none"><li>• Tell your doctor if you drink alcohol.</li></ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"><li>• Keep Valaciclovir RBX tablets in a cool dry place where the temperature stays below 25°C.</li><li>• Keep your tablets in the packaging until it is time to take them.</li></ul>

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

### 6. Are there any side effects?

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.

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.

# Valaciclovir RBX

Active ingredient(s): *Valaciclovir hydrochloride*

## Consumer Medicine Information (CMI)

This leaflet provides important information about using Valaciclovir RBX. **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 Valaciclovir RBX.**

Where to find information in this leaflet:

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

## 1. Why am I using Valaciclovir RBX?

**Valaciclovir RBX Tablets contains the active ingredient valaciclovir hydrochloride and belong to a group of medicines called antivirals.**

Valaciclovir RBX tablets are used for the treatment of genital herpes, shingles (herpes zoster), ophthalmic zoster (shingles affecting the eye region). It also used to prevent cytomegalovirus (CMV) infection and disease following solid organ transplantation. CMV is another type of herpes virus that can cause symptoms similar to glandular fever (high temperature, sore throat and swollen glands).

Valaciclovir RBX tablets work by stopping the multiplication of the virus which causes herpes and shingles. It can reduce the length and severity of an outbreak and duration of pain, and shorten the healing time of crusts, associated with herpes and shingles. Valaciclovir RBX does not eliminate the herpes virus (Herpes Simplex Virus or HSV) from the body.

It is important the treatment for shingles is started within the first three days of the shingles attack.

For the treatment of herpes simplex, start taking the tablets as soon as you feel an outbreak starting, as you may prevent the blisters from developing, or help the blisters to heal more quickly.

Valtrex tablets can also be taken long term to help prevent or reduce recurrent outbreaks of HSV and reduce the risk of transmitting the virus that causes genital herpes but does not cure or completely eliminate the risk of transmission.

Valtrex tablets are more effective in patients 50 years of age and older.

Ask your doctor if you have any questions about why Valtrex tablets have been prescribed for you.

Valtrex tablets are available only with a doctor's prescription.

Valtrex tablets are not addictive

### Use in children

There is not enough information to recommend the use of Valtrex in children.

## 2. What should I know before I use Valaciclovir RBX?

### Warnings

#### Do not use Valaciclovir RBX if:

- you are allergic to Valaciclovir, or aciclovir or any of the ingredients listed at the end of this leaflet.
- always check the ingredients to make sure you can use this medicine.  
Some of the symptoms of an allergic reaction may include: 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.
- you are pregnant, trying to become pregnant, or breastfeeding.
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

#### Check with your doctor if you:

- have any other medical conditions
- allergies to any other medicines, foods, preservatives or dyes.
- take any medicines for any other condition
- are pregnant, trying to become pregnant or breastfeeding unless your doctor says you should.

#### Tell your doctor if you have or have had the following medical conditions:

- kidney or liver problem.
- anaemic (reduced red blood cells or iron stores).
- skin reactions with valaciclovir which may include a rash, fever, facial swelling or blistering/peeling skin.

Care should be taken to ensure adequate fluid intake in patients who are at risk of dehydration, such as the elderly.

Immunocompromised patients with ophthalmic zoster or those with a high risk for disease dissemination and visceral organ involvement should be treated with intravenous antiviral therapy

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

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.

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

Your doctor can discuss with you the risks and benefits involved.

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

**Some medicines may interfere with Valaciclovir RBX and affect how it works.**

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.

Tell your doctor if you are taking any of the following medicines:

- mycophenolate mofetil
- cyclosporin
- tacrolimus
- aminoglycosides
- organoplatinum compounds
- iodinated contrast media
- methotrexate
- pentamidine
- foscarnet

These medicines may be affected by Valaciclovir RBX or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Some of the medicines above are commonly taken by transplant patients and require close attention.

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 Valaciclovir RBX.**

## 4. How do I use Valaciclovir RBX?

**Follow all directions given to you by your doctor or pharmacist carefully.**

They may differ from the information contained in this leaflet.

**Your doctor or pharmacist will tell you:**

- how many tablets to take at each dose

- how many doses to take each day
- when to take your doses each day.

**If you do not understand the directions, ask your doctor or pharmacist for help.**

## How much to take Valaciclovir RBX

Your doctor will decide what dose you should take and how often you should take Valaciclovir RBX tablets. The dosage may vary depending on your medical history.

### Treatment of Herpes Zoster (shingles)

The usual dose is 2 Valaciclovir RBX tablets (each containing 500 mg of valaciclovir) three times a day.

### Treatment of genital herpes

If you are suffering from genital herpes infection for the first time, the dose usually given is one Valaciclovir RBX tablet (containing 500 mg of valaciclovir) two times a day.

If you have had a herpes infection before, the dose usually given is one Valaciclovir RBX tablet (containing 500 mg of valaciclovir) two times a day.

You should start to take Valaciclovir RBX tablets as early as possible if you think you are about to have a recurrence (attack) of genital herpes. Dosing should ideally start just before, or straight after the first signs of genital herpes infection appear.

### Prevention of genital herpes in immunocompromised patients

To prevent the herpes infection appearing again, the usual dose to take is one Valaciclovir RBX tablet (containing 500 mg of valaciclovir) two times a day.

### Reduction of risk of transmission of genital herpes

In adults with normal immune function with less than 10 recurrences of genital herpes infection per year, the usual dose for the infected partner is one Valaciclovir RBX tablet (containing 500 mg of valaciclovir) taken once daily.

### Prevention of CMV infection and disease

The usual dose for adults and children over 12 years of age is four 500 mg tablets four times a day for 90 days.

**If you have liver or kidney problems:** Your dosage would be different if you have liver or kidney problems and your doctor will decide the dose and duration of treatment for you

**If you are elderly:** your dose may be adjusted by your doctor according to your kidney function.

**If you think you have been advised to take a different dose, talk to your doctor or pharmacist.**

## When to take Valaciclovir RBX

Take your Valaciclovir RBX tablets at about the same time each day. Taking your tablets at the same time each day will have the best effect. It will also help you to remember when to take the tablets.

### For the prevention of CMV infection and disease

The tablets should be taken four times a day (i.e. morning, noon, afternoon and evening).

### For the treatment of shingles

The usual times to take the tablets are in the morning, afternoon and evening.

### For the treatment of herpes simplex infections (genital herpes)

The usual times to take the tablets are in the morning and evening.

## How to take Valaciclovir RBX

Valaciclovir RBX tablets are to be taken orally. Swallow the tablet whole with a full glass of water.

You should drink plenty of fluids while on treatment with Valaciclovir RBX, especially if you are elderly.

### How long to take Valaciclovir RBX

**For the treatment of shingles:** The usual course of treatment is 7 days.

**For the treatment of genital herpes infections,** The usual course of treatment is 5 days. However in some instances your doctor may want you to take your tablets for 10 days.

**For prevention of genital herpes infections in immunocompromised patients with moderate to normal kidney function and reduction of risk of transmission of the genital herpes infection:** You should continue to take this medicine as long as prescribed by your doctor.

**For the prevention of CMV infection and disease:** The usual course of treatment is 90 days.

**Continue taking the medicine as long as the Doctor has told you to. Do not stop taking the Valaciclovir RBX tablets before the course of treatment is finished just because you feel better. If you stop too soon, the infection may start again.**

### If you forget to take Valaciclovir RBX

Valaciclovir RBX should be taken regularly at the same time each day. If you miss your dose at the usual time and if it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

**Do not take a double dose to make up for the dose that you missed.**

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints.

### If you use too much Valaciclovir RBX

If you think that you have used too much Valaciclovir RBX, you may need urgent medical attention.

**You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), 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.**

## 5. What should I know while using Valaciclovir RBX?

### Things you should do

- Tell your doctor, dentist or pharmacist that you are taking Valaciclovir RBX tablets if you are about to be started on any new medicines.
- If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.
- Tell your doctor if you become pregnant or are trying to become pregnant or intend to breast-feed while you are taking Valaciclovir RBX tablets.
- Drink plenty of fluids while you are taking Valaciclovir RBX tablets.
- Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed. Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.
- 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.
- Keep all your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

**It is recommended that patients using Valaciclovir RBX continuously to prevent or reduce recurrent outbreaks, or to reduce the risk of transmitting the virus that causes genital herpes, also avoid contact when symptoms are present and always use condoms.**

Valaciclovir RBX does not cure genital herpes or completely eliminate the risk of transmission. Because

genital herpes is a sexually transmitted disease, you should minimise having intercourse when you have an outbreak of herpes or show any symptoms. This will avoid the risk of spreading herpes to your partner.

### Things you should not do

- Do not stop taking VALaciclovir RBX tablets, or alter the dose, without first checking with your doctor.
- Do not give this medicine to anyone else, even if their symptoms seem similar to yours.
- Do not use VALACICLOVIR RBX tablets to treat any other complaints unless your doctor tells you to.

### Driving or using machines

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

### Drinking alcohol

**Tell your doctor if you drink alcohol**

### Looking after your medicine

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

Keep your tablets in the blister pack until it is time to take them.

Store it in a cool dry place. away from moisture, heat or sunlight where it stays below 25°C.

Heat and dampness can destroy some medicines.

Do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

### Keep it where young children cannot reach it.

A locked cupboard at least one-and-a-half meters above the ground is a good place to store medicines.

### When to discard your medicine (as relevant)

If your doctor tells you to stop taking Valtrex, or the tablets have passed their expiry date, ask your pharmacist what to do with any tablets left over. **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

## 6. Are there any side effects?

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.

Check with your doctor as soon as possible if you have any problems while taking this medicine, even if you do not think the problems relate to the medicine or are not listed in this leaflet.

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

### Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> <li>• headache</li> <li>• gastrointestinal discomfort (vomiting, nausea, diarrhoea, constipation, abdominal pain, indigestion, flatulence)</li> <li>• dry mouth</li> <li>• fever</li> <li>• difficulty sleeping</li> <li>• chills</li> <li>• back pain</li> <li>• nervousness</li> <li>• skin rash which may be itchy</li> <li>• weakness</li> </ul>	<p><b>Speak to your doctor if you have any of these less serious side effects and they worry you.</b></p>

### Serious side effects

Serious side effects	What to do
<p><b>Some of these side effects are more common in patients with kidney disease or in those taking high doses of Valtrex:</b></p> <ul style="list-style-type: none"> <li>• sensitivity to UV light, which may include development of a rash-like sunburn even after short period of exposure to UV or sunlight</li> <li>• dizziness, confusion, imagining sights or sounds (hallucinations), difficulty in thinking</li> <li>• drowsiness or decreased consciousness</li> <li>• tiredness, dizziness, or being short of breath when exercising (signs of anaemia)</li> <li>• high blood pressure</li> <li>• damage to the kidney, which gets better when Valaciclovir RBX treatment is stopped</li> <li>• unusual bruising or bleeding. Tell your doctor immediately if you notice any bruising or bleeding, as it may indicate that the number of platelets (a type of blood cell responsible for blood clotting) in your blood are reduced</li> <li>• skin reactions which may include a rash, fever, facial swelling or blistering or peeling skin</li> <li>• renal pain, acute renal failure and tubulointerstitial nephritis (elderly population)</li> <li>• damage to the liver, which gets better when Valaciclovir RBX treatment is stopped.</li> <li>• agitation or tremor</li> </ul>	<p><b>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.</b></p>

<ul style="list-style-type: none"> <li>uncoordinated eye and muscle movements and speech or difficulty speaking</li> <li>psychotic episodes</li> <li>convulsions or seizures or coma</li> <li>brain injury</li> <li>symptoms of an allergic reaction including cough, shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body; rash, itching or hives on the skin</li> <li>some other side effects may occur in some people, for example changes in kidney or liver function, can only be found when your doctor does tests from time to time to check your progress.</li> </ul>	
---	--

	hypromellose, titanium dioxide, macrogol 400, macrogol 6000, polysorbate 80 and indigo carmine aluminum lake (30-36%)
--	---

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

### What Valaciclovir RBX looks like

Valaciclovir RBX tablets are available as blue coloured, capsule-shaped, biconvex, film-coated tablets, debossed with 'V' and '5' on either side of the break line on one side, notched on either side along with the break line and plain on the other side containing valaciclovir (as hydrochloride) 500 mg.

Valaciclovir RBX tablets are available in blister packs containing 30, 42 or 100 tablets (Aust R 142803).

**Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell, even if it is not on this list**

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

Ask your doctor or pharmacist any questions you may have.

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

### 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.

### What Valaciclovir RBX contains

<b>Active ingredient (main ingredient)</b>	valaciclovir hydrochloride
<b>Other ingredients (inactive ingredients)</b>	<ul style="list-style-type: none"> <li>microcrystalline cellulose</li> <li>magnesium stearate</li> <li>crospovidone</li> <li>povidone (K 30)</li> <li>povidone (K 90D)</li> <li>indigo carmine aluminum lake (11-14%)</li> <li>Opadry O2C50740 Blue which consists of</li> </ul>

### Who distributes Valaciclovir RBX

Sun Pharma ANZ Pty Ltd.

12 Waterloo Road,

Macquarie Park

NSW 2113, Australia

Email: [customerservice.aus@sunpharma.com](mailto:customerservice.aus@sunpharma.com)

Tel: 1800 726 229

This leaflet was prepared in Nov 2024