

APX-VALACICLOVIR

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 APX-Valaciclovir?

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

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

2. What should I know before I use APX-Valaciclovir?

Do not use if you have ever had an allergic reaction to valaciclovir or aciclovir 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 APX-Valaciclovir?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APX-Valaciclovir 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 APX-Valaciclovir?

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.

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

5. What should I know while using APX-Valaciclovir?

Things you should do	<ul style="list-style-type: none">• Remind any doctor, dentist or pharmacist you visit that you are using APX-Valaciclovir• Drink plenty of fluids while you are taking this medicine.
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly• Do not use this medicine to treat any other complaints unless your doctor says to.
Driving or using machines	<ul style="list-style-type: none">• Be careful before you drive or use any machines or tools until you know how APX-Valaciclovir affects you.
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol.
Looking after your medicine	<ul style="list-style-type: none">• Keep APX-Valaciclovir tablets in a cool, dry place where it stays below 30°C.• Heat and dampness can destroy some medicines.• Keep your tablets in their pack until it is time to take them. If you take the tablets out of their pack, they may not keep well.

For more information, see Section [5. What should I know while using \[insert medicine\]?](#) 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

APX-VALACICLOVIR

Active ingredient(s): *valaciclovir hydrochloride*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APX-Valaciclovir. **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 APX-Valaciclovir.**

Where to find information in this leaflet:

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

1. Why am I using APX-Valaciclovir?

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

APX-Valaciclovir tablets work by stopping the multiplication of the virus which causes herpes, shingles and cold sores. It can reduce the length and severity of an outbreak and duration of pain, and shorten the healing time

of crusts, associated with herpes, shingles and cold sores. APX-Valaciclovir 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 cold sores, the tablets should be taken at the earliest symptom of a cold sore (e.g. tingling, itching, or burning).

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.

APX-Valaciclovir 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.

APX-Valaciclovir tablets are more effective in patients 50 years of age and older.

Ask your doctor if you have any questions about why APX-Valaciclovir tablets have been prescribed for you.

APX-Valaciclovir tablets are available only with a doctor's prescription.

APX-Valaciclovir tablets are not addictive

Use in children

There is not enough information to recommend the use of APX-Valaciclovir in children.

2. What should I know before I use APX-Valaciclovir?

Warnings

Do not use APX-Valaciclovir if you have ever had an allergic reaction to:

- valaciclovir or aciclovir
- any of the ingredients listed at the end of this leaflet
- 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

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 any of the following medical conditions:

- kidney or liver conditions
- are anaemic (reduced red blood cells or iron stores)

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

- previous skin reactions with valaciclovir which may include a rash, fever, facial swelling or blistering/peeling skin

If you have not told your doctor about any of the above, please do so before you take APX-Valaciclovir.

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.

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.

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
- tenofovir
- cimetidine
- probenecid

These medicines may be affected by APX-Valaciclovir 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.

Do not take APX-Valaciclovir tablets after the expiry date (EXP) printed on the pack.

If you take it after the expiry date has passed, it may not work as well. who are at risk of dehydration, such as the elderly.

Do not take APX-Valaciclovir tablets if the packaging is torn or shows signs of tampering.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect APX-Valaciclovir.

4. How do I use APX-Valaciclovir?

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

They may differ from the information contained in this leaflet.

How much to take

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.

For the 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 a kidney disease your doctor may reduce your dose.

For the treatment of shingles

500 mg tablets: The normal dose to take is two tablets with water three times a day.

For the treatment of cold sores

500 mg tablets: The normal dose to take for the one-day regimen is four tablets with water twice a day, with the second dose taken about 12 hours after the first dose.

For the treatment of acute (short term) genital herpes:

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

500 mg tablets: For the treatment of HSV infection, the usual dose to take is one tablet with water twice daily.

For suppressive (long term) treatment of genital herpes:

500mg tablets: To prevent the herpes infection appearing again, the usual dose to take is 500 mg once daily. Your doctor may recommend that you take this as a divided dose (i.e. 250 mg twice daily).

If you previously have had more than 10 recurrences (attacks) in one year, your doctor may recommend that you take 1000 mg of APX-Valaciclovir once daily to prevent recurrences.

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

When to take APX-Valaciclovir

It does not matter if you take this medicine before or after food.

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 cold sores

The tablets should be taken at the earliest symptom of a cold sore (e.g. tingling, itching, or burning). Treatment for cold sores should not exceed 1 day (2 doses) and the doses should be taken 12 hours apart. The shingles and cold sore packs are designed to help you to remember to take the tablets at the correct times.

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 APX-Valaciclovir

- Swallow the tablets with a glass of water. You should drink plenty of fluids while taking APX-Valaciclovir tablets, especially if you are elderly

How long to take them

For the prevention of CMV infection and disease

The usual course of treatment is 90 days.

For the treatment of shingles

The usual course of treatment is 7 days

Do not stop taking APX-Valaciclovir tablets before the course of treatment is finished just because you feel better. The shingles may not be completely over.

For the treatment of cold sores

The course of treatment should not exceed 1 day (2 doses) and the doses should be taken 12 hours apart.

For the treatment of herpes simplex (genital herpes)

For the treatment of 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 the prevention of herpes infections

You should continue to take this medicine every day as prescribed by your doctor.

Do not stop taking APX-Valaciclovir tablets just because you feel better. The herpes outbreak may not be completely over.

If you forget to use APX-Valaciclovir

APX-Valaciclovir should be used regularly at the same time each day.

For prevention of CMV infection and disease, the treatment of shingles or the treatment of herpes simplex (genital herpes)

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.

For the treatment of cold sores

Take the second dose as soon as possible once 12 hours have passed.

If you miss more than one dose, or you are not sure what to do ask your doctor or pharmacist.

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

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.

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

If you use too much APX-Valaciclovir

If you think that you have used too much APX-Valaciclovir, 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 APX-Valaciclovir?

Things you should do

Drink plenty of fluids while you are taking this medicine.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Call your doctor straight away 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.
- become pregnant or are trying to become pregnant or intend to breastfeed while you are taking this medicine.
- for any reason you have not taken your medicine exactly as prescribed.

Remind any doctor, dentist or pharmacist you visit that you are using APX-Valaciclovir. 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 APX-Valaciclovir 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.

APX-Valaciclovir 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 using this medicine suddenly 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 this medicine to treat any other complaints unless your doctor says to.

Driving or using machines

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

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

- Keep APX-Valaciclovir tablets in a cool, dry place where it stays below 30°C.
- A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.
- Heat and dampness can destroy some medicines.
- Keep your tablets in their pack until it is time to take them. If you take the tablets out of their pack, they may not keep well.

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

Store it in a cool dry place away from moisture, heat or sunlight; for example, 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.

When to discard your medicine (as relevant)

If your doctor tells you to stop taking APX-Valaciclovir, 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"> • headache • gastrointestinal discomfort (vomiting, nausea, diarrhoea, constipation, abdominal pain, indigestion) • dry mouth • fever • difficulty sleeping • chills • back pain • nervousness • skin rash, which may be itchy • weakness 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Some of these side effects are more common in patients with kidney disease or in those taking high doses of APX-Valaciclovir:</p> <ul style="list-style-type: none"> • sensitivity to UV light, which may include development of a rash-like sunburn even after short period of exposure to UV or sunlight • dizziness, confusion, imagining sights or sounds (hallucinations), difficulty in thinking • drowsiness or decreased consciousness • tiredness, dizziness, or being short of breath when exercising (signs of anaemia) • high blood pressure • thrombotic thrombocytopenic purpura • haemolytic uraemic syndrome • neurological disorders <p>If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:</p> <ul style="list-style-type: none"> • damage to the kidney, which gets better when APX-Valaciclovir treatment is stopped 	<p>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.</p>

<ul style="list-style-type: none"> • 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 	
Serious side effects	What to do
<ul style="list-style-type: none"> • skin reactions which may include a rash, fever, facial swelling or blistering or peeling skin • renal pain, acute renal failure and tubulointerstitial nephritis (elderly population) • damage to the liver, which gets better when APX-Valaciclovir treatment is stopped. • agitation or tremor • uncoordinated eye and muscle movements and speech or difficulty speaking • psychotic episodes • convulsions or seizures or coma • brain injury • 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 • Drug reaction with eosinophilia and systemic symptoms (DRESS) • 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. 	<p>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.</p>

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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. 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

What APX-Valaciclovir contains

Active ingredient (main ingredient)	APX-Valaciclovir tablets contain the active ingredient valaciclovir hydrochloride
Other ingredients (inactive ingredients)	<ul style="list-style-type: none">• microcrystalline cellulose• crospovidone• povidone• colloidal anhydrous silica• carnauba wax• magnesium stearate• Opadry YS-19043 (white colour concentrate)

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

What APX-Valaciclovir looks like:

- **APX-Valaciclovir 500mg:** White, film coated tablet, white to off-white core, biconvex, elongated, unscored engraved with "500" on one side and plain on the other. AUST R 335725 (bottle pack) & AUST R 335726 (blister pack).
- **APX-Valaciclovir 1000mg tablets:** White, film coated tablet, white to off-white core, biconvex, elongated, with a partial score bar on both sides, engraved with "1000" on one side and plain on the other. AUST R 335727

Available in a pack size of 2 (starter pack), 4, 6, 10, 20, 21, 30, 42, 60, 80, 90, 100, 240, 480, 500, 8x500, 4x1000 tablets*

*Not all pack sizes may be available or marketed

Who distributes APX-Valaciclovir

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

www.arrotex.com.au

This leaflet was prepared in January 2026.