

APO-Valaciclovir

for cytomegalovirus

Valaciclovir hydrochloride monohydrate

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

This leaflet answers some common questions about valaciclovir. 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 using this medicine against the benefits they expect it will have for you.

Keep this leaflet with your medicine.

You may want to read it again.

What this medicine is used for

Valaciclovir belongs to a group of medicines called antivirals.

Valaciclovir is used to prevent cytomegalovirus (CMV) infection and disease, following solid organ transplantation.

CMV is another type of herpes virus. It can cause symptoms similar to glandular fever (high temperature, sore throat and swollen glands).

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

Your doctor may have prescribed this medicine for another reason.

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

This medicine is not addictive.

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

Before you take this medicine

When you must not take it

Do not take this medicine if you have had an allergy to:

- valaciclovir
- aciclovir

- any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include:

- 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.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

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

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you have or have had any medical conditions, especially the following:

- kidney or liver disease
- anaemia (reduced red blood cells or iron stores)

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

Tell your doctor if you are currently pregnant or you plan to become pregnant, or are breastfeeding.

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

If you have not told your doctor about any of the above, tell him/her before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get from your pharmacy, supermarket or health food shop.

Some medicines and valaciclovir interfere with each other. These include:

- mycophenolate mofetil, cyclosporin and tacrolimus, medicines commonly taken by transplant patients
- aminoglycoside antibiotics, such as gentamicin
- pentamidine, used to treat or prevent certain infections
- foscarnet, used against viruses
- methotrexate, used for conditions such as rheumatoid arthritis

- organoplatinum compounds, used in cancer
- iodine based contrast media for scans

These medicines may be affected by this medicine 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 and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

Other medicines not listed above may also interact with valaciclovir.

How to take this medicine

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

They may differ to the information contained in this leaflet.

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

How much to take

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

How to take it

Swallow the tablets whole with a full glass of water. You should drink plenty of fluids whilst taking valaciclovir, especially if you are elderly.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

To prevent CMV infection and disease, the tablets should be taken four times a day (i.e. morning, noon, afternoon and evening).

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

How long to take it for

Continue taking your medicine for as long as your doctor tells you.

For the prevention of CMV infection and disease, the usual course of treatment is 90 days.

Do not stop taking it unless your doctor tells you to, even if you feel better.

Make sure you have enough to last over weekends and holidays.

If you forget to take it

If it is almost time to take 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 your medicine as you would normally.

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

This may increase the chance of side effects.

If 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 to help you remember.

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 at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Signs of an overdose with valaciclovir may include:

- acute renal failure which may present as: decreased urine; fluid retention causing swollen legs, ankles or feet; nausea; drowsiness; fatigue; difficulties breathing.
- confusion, hallucinations, agitation, decreased consciousness and coma
- nausea and vomiting

While you are taking this medicine

Things you must do

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

Tell any other doctors, dentists, and pharmacists who are treating you that you are taking valaciclovir.

If you become pregnant while taking valaciclovir, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may occasionally do tests to make sure the medicine is working and to prevent side effects.

Things you must not do

Do not take your medicine to treat any other complaints unless your doctor tells you to.

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

Do not stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how valaciclovir affects you.

This medicine may cause dizziness and drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Side effects

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

This medicine helps most people, but it may have 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 attention if you get some of the side effects.

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

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

Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor if you notice any of the following:

- headache
- gastrointestinal discomfort (vomiting, nausea, diarrhoea, constipation, abdominal pain, indigestion)
- dry mouth
- nervousness
- drowsiness
- increase in blood pressure
- swelling
- difficulty sleeping
- muscle aches, pain or weakness

The above list includes the more common side effects of your medicine.

Tell your doctor as soon as possible if you notice any of the following:

- decreased consciousness, dizziness, weakness
- fever, chills, infections or flu like symptoms
- back or joint pain
- skin rash, which may be itchy
- sensitivity to UV light, such as development of a rash like sunburn even after short exposure to UV light

The above list includes serious side effects that may require medical attention.

If any of the following happen, tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- allergic reaction, which may present as: 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
- damage to the kidney, which may present as: decreased urine; fluid retention causing swollen legs, ankles or feet; nausea; drowsiness; fatigue; difficulties breathing
- damage to the liver, which may present as: nausea and vomiting; loss of appetite; feeling generally unwell; fever; itching; yellowing of the skin and eyes; dark coloured urine

- unusual bruising or bleeding, which may indicate that the number of platelets (a type of blood cell responsible for blood clotting) in your blood are reduced
- coma
- agitation, tremor
- uncoordinated eye and muscle movements, difficulty speaking
- confusion, difficulty thinking, imagining sights or sounds (hallucinations), psychotic episodes
- convulsions or seizures.

These are very serious side effects and you may need urgent medical attention or hospitalisation.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may occur in some patients.

Storage and disposal

Storage

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

If you take the tablets out of the pack they may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

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

Disposal

If your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What APO-Valaciclovir looks like

500 mg tablets

Dark blue, capsule-shaped, biconvex film-coated tablets, engraved "APO" on one side, "VAL 500" on the other side.

Blisters of 2, 4, 6, 8, 10, 20, 30, 42, 60, 80, 90, 100, tablets and bottles of 100 tablets.

1000mg tablets

White, oval shaped, biconvex film-coated tablet, partially scored and engraved "APO" on one side, "VAL 1000" on the other side.

Blisters of 3, 4, 21 tablets and bottles of 4 and 100 tablets.

Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains valaciclovir as the active ingredient.

It also contains the following:

- Stearic Acid
- Colloidal Anhydrous Silica
- Hypromellose
- Macrogol 8000
- Titanium Dioxide
- Indigo Carmine Aluminium Lake

This medicine is free from gluten, lactose, sucrose, tartrazine and other azo dyes.

Australian Registration Numbers

APO-Valaciclovir 500 mg tablets (blister pack): AUST R 158911

APO-Valaciclovir 500 mg tablets (bottle): AUST R 158910

APO-Valaciclovir 1000 mg tablets (bottle): AUST R 158907

Sponsor

Apotex Pty Ltd

16 Giffnock Avenue

Macquarie Park, NSW 2113

APO and APOTEX are registered trade marks of Apotex Inc.

This leaflet was prepared in

July 2018.