

APX-VALACICLOVIR Tablets

for herpes zoster, herpes labialis, herpes simplex and cytomegalovirus

valaciclovir hydrochloride

Consumer Medicine Information

What is in this leaflet

This leaflet answers some common questions about APX-VALACICLOVIR tablets. It does not contain all of 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 APX-VALACICLOVIR tablets against the benefits this medicine is expected to have for you.

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

Keep this leaflet with the medicine.

You may need to read it again.

What APX-VALACICLOVIR tablets are used for

How APX-VALACICLOVIR tablets work

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.

Before you take APX-VALACICLOVIR tablets

When you must not take them

Do not take APX-VALACICLOVIR tablets 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

Do not take APX-VALACICLOVIR tablets if you are pregnant, trying to become pregnant or breastfeeding unless your doctor says you should.

Your doctor will discuss the risks and benefits of using APX-VALACICLOVIR tablets when pregnant and during breastfeeding.

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.

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

If you are not sure whether you should be taking APX-VALACICLOVIR, talk to your doctor.

Before you start to take them

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 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 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

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

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

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

Taking other medicines

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.

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 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.

How to take APX-VALACICLOVIR tablets

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

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.

1000 mg tablets: The normal dose to take is one tablet 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.

1000 mg tablets: The normal dose to take for the one-day regimen is two 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:

500 mg 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.

How to take them

Swallow the tablets with a glass of water.

You should drink plenty of fluids while taking APX-VALACICLOVIR tablets, especially if you are elderly.

When to take them

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 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 take them

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.

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

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 you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126) for advice, if you think you or anyone else may have taken too much APX-VALACICLOVIR tablets, even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

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

While you are taking APX-VALACICLOVIR tablets

Things you must 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.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

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 breastfeed while you are taking this medicine.

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 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 must not do

Do not stop taking this medicine, 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.

Things to be careful of

Be careful driving or operating machinery until you know how this medicine affects you.

Side Effects

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.

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

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.

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 or pharmacist if you notice any of the following and they worry you:

- 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

Tell your doctor as soon as possible if you notice any of the following. Some of these side effects are more common in patients with kidney disease or in those taking high doses of APX-VALACICLOVIR:

- 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

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

- damage to the kidney, which gets better when APX-VALACICLOVIR treatment is stopped
- 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
- skin reactions which may include a rash, fever, facial swelling or blistering or peeling skin
- 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

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also occur in some people.

Some of these side effects, 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.

After taking APX-VALACICLOVIR tablets

Storage

Keep this medicine where young children cannot reach it.

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

Keep APX-VALACICLOVIR tablets in a cool, dry place where it stays below 30°C. Do not store them, or any other medicine, in a bathroom or near a sink.

Do not leave them in the car or on windowsills.

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.

Disposal

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.

Product description

What APX-VALACICLOVIR tablets look like.

APX-VALACICLOVIR 500 mg tablets

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 335726 (blister pack).

AUST R 335725 (bottle).

Available in a pack size of 10, 30, 42 and 100 tablets.

APX-VALACICLOVIR 1000 mg tablets

White, film coated tablet, white to off-white core, biconvex, elongated, unscored engraved with “1000” on one side and plain on the other.

AUST R 335727 (blister).

Available in a pack size of 4 tablets.

Ingredients

APX-VALACICLOVIR tablets contain the active ingredient valaciclovir hydrochloride.

The tablets also contain:

- microcrystalline cellulose
- crospovidone
- povidone
- colloidal anhydrous silica
- carnauba wax
- magnesium stearate
- Opadry YS-19043 (white colour concentrate)

Supplier

Arrotex Pharmaceuticals Pty Ltd
15-17 Chapel Street
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