

APO-Aciclovir 200 mg & 800 mg Tablets

Contains the active ingredient aciclovir

Consumer Medicine Information

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

What is in this leaflet

Read this leaflet carefully before taking your medicine.

This leaflet answers some common questions about aciclovir. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

You can also download the most up to date leaflet from www.apotex.com.au.

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.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Aciclovir. It contains the active ingredient aciclovir.

The 200mg strength is used to

- treat genital herpes. It makes an outbreak of genital herpes shorter and less severe
- prevent or reduce the number of outbreaks and/or severity of genital herpes in people who experience them often.

The 800mg strength is used:

- to treat shingles, also known as herpes zoster. Shingles is caused by the same virus which causes chicken pox. It usually involves nerve pain and a blistering rash, limited to one area of the body. If taken within 72 hours of first getting the rash, aciclovir makes an outbreak of shingles shorter and less severe
- as part of the management program for certain infections in people who have the human immunodeficiency virus (HIV). HIV is the virus that causes acquired immune deficiency syndrome (AIDS). Aciclovir does not cure AIDS or get rid of the HIV virus from your body, but it may prevent further damage to the immune system by stopping production of the herpes viruses.

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.

How it works

Aciclovir belongs to a group of medicines called "anti-virals". It works by stopping the production of the virus that causes herpes and shingles.

Aciclovir does not get rid of the virus from your body.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, aciclovir, valaciclovir or 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; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

- **The expiry date (EXP) printed on the pack has passed.**
- The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
 - kidney or liver problems
 - neurological disorders such as muscle weakness, paralysis, seizures, confusion, etc
 - an imbalance of electrolytes (salts) in your body
 - severe lack of oxygen from any part of your body
 - neurological reactions from a cytotoxic (anti-cancer) medicine.
3. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
4. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your

doctor have discussed the risks and benefits involved.

5. You are planning to have surgery or an anaesthetic.
6. You are currently receiving or are planning to receive dental treatment.
7. You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with aciclovir. These include:

- probenecid, a medicine commonly used to treat gout
- cimetidine, used for stomach problems
- diuretics, also called fluid tablets
- interferon, used to treat multiple sclerosis, hepatitis, leukaemia, Hodgkin's lymphoma and other diseases
- methotrexate given by injection into the spine to treat cancer and leukaemia
- mycophenolate mofetil, used by people with organ transplants.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with aciclovir.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The doses below may be lower if you have problems with your kidneys.

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

Initial genital herpes

The usual dose is one 200mg tablet every four hours, while awake, for a total of five tablets daily for ten days.

Recurrent genital herpes

The usual dose is one 200mg tablet three times a day for up to six months.

Or

One 200mg tablet every four hours, while awake, for a total of five tablets daily for five days.

Shingles

The usual dose is one 800mg tablet every four hours, while awake, for a total of five tablets daily for seven days (or up to ten days if your eyes are affected by shingles).

Management of HIV

The usual dose is one 800mg tablet four times a day at six hourly intervals.

How to take it

The tablets should be swallowed whole with a glass of water.

When to take it

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

It does not matter if you take it before, with or after food.

How long to take it for

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

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 missed dose and take your next dose at the usual time.

Otherwise, take it as soon as you remember and 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 you experiencing side effects.

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)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take too much of this medicine, you may feel or be sick, have a headache and/or feel confused.

While you are taking this medicine

Things you must do

If you feel that your condition is not improving or is getting worse, see your doctor.

Tell your doctor that you are taking this medicine if:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are about to have any blood tests

- you are going to have surgery or are going into hospital.

Your doctor may occasionally do tests on your blood or urine to check for side effects and see how your kidneys are working. Go to your doctor regularly for a check-up.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Genital herpes and HIV can be transmitted to your partner during sexual activity. It is important to remember that this medicine will not keep you from transmitting herpes or HIV to others.

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

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking aciclovir or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following:

- stomach problems such as nausea (feeling sick), vomiting (being

sick), diarrhoea, constipation, stomach pain

- changes in taste sensation, loss of appetite, weight loss
- dizziness/giddiness or headache
- difficulty sleeping
- increased hair loss
- weakness, fatigue, lack of energy, tiredness
- aching, leg pains, muscles pains, joint pain, muscle cramps
- menstrual problems.

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

These may be serious side effects. You may need medical attention.

- confusion
- depression, agitation, irritability
- unusual thoughts or actions, hallucinations (seeing, feeling or hearing things that are not there)
- shakiness/trembling
- difficulty speaking
- uncoordinated movements, i.e. unsteady walking
- fever, sore throat, swollen glands
- blood problems (e.g. feeling tired and weak, fever, frequent infections, unusual bruising or bleeding or swelling around wounds)
- fluid retention
- eye problems (inflamed eye).

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

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

- yellowing of the skin and/or eyes (jaundice) or other liver problems with a collection of symptoms which may include: mental confusion, drowsiness, restlessness, itching and unconsciousness

- kidney problems e.g. too much or too little urine, or pain when urinating, or pain in the kidneys
- troubled breathing
- chest pain, fast heart beat (palpitations)
- convulsion (fits)
- losing consciousness or in a coma
- signs of a blood clot such as a swollen and painful area in your leg, and swelling in your foot or ankle.

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

Allergic reactions

If you think you are having an allergic reaction to aciclovir, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:

- cough, 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
- fainting
- hayfever-like symptoms.

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it 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 this medicine 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 they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO-Aciclovir looks like

APO-Aciclovir 200mg tablets are round, blue, flat-faced, bevel-edged tablets, engraved "APO" over "200" on one side and the other side plain.

Blister packs of 25, 50 and 90 tablets.*

APO-Aciclovir 800mg tablets are oval, blue, biconvex tablet. Engraved APO partial bisect 800 on one side, plain on the other side. Blister packs of 35 tablets.

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

Ingredients

Each tablet contains 200mg or 800mg of aciclovir as the active ingredient.

It also contains the following inactive ingredients:

- lactose (for the 200mg strength only)
- magnesium stearate
- colloidal anhydrous silica
- croscarmellose sodium
- microcrystalline cellulose
- indigo carmine
- brilliant blue FCF (for the 800mg strength only).

The 200 mg tablets are gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

The 800 mg tablets are lactose-free, gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Aciclovir 200mg tablets:

AUST R 159140.

APO-Aciclovir 800mg tablets:

AUST R 159141.

Sponsor

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