Consumer Medicine Information

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. Some more recent

information on the medicine may be available. You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine

All medicines have risks and benefits. Your doctor has weighed the risks of you taking aciclovir against the benefits he/she expects it will have for you.

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

Keep this leaflet with the medicine.

You may want to read it again.

Statements made in this leaflet cannot be applied to any other medicine, even if they appear to be similar or contain the same ingredients.

What Aciclovir is used for

The name of your medicine is Aciclovir 200. It contains the active ingredient, aciclovir.

Aciclovir is used to treat genital herpes. It makes an outbreak of genital herpes shorter and less severe

It can also be used long term to prevent or reduce the number of outbreaks of genital herpes in people who experience them often.

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.

How it works

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

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

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

There is no evidence that this medicine is addictive.

This medicine is not expected to affect your ability to drive a car or operate machinery, but make sure you know how it affects you before driving.

Use in children

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

Before you take Aciclovir

When you must not take it

Do not take this medicine if:

 you have an allergy to aciclovir (the active ingredient) or valaciclovir.

- you are allergic to 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 o difficulty breathing, swelling of the face,
- the expiry date (EXP) printed on the pack has passed

lips, tongue or other parts of the body, and

- If you take this medicine after the expiry date has passed, it may not work as well.
- the packaging is torn or shows signs of tampering.

rash, itching or hives on the skin.

 the tablets change in appearance, colour or taste

If it has expired or is damaged or does not seem quite right, return it to your pharmacist for disposal.

If you are not sure whether you should start taking Aciclovir, talk to your doctor.

Before you start to take it

Tell your doctor, and discuss the risks and benefits of taking Aciclovir if:

- 1. you are allergic to any other medicines, foods, preservatives or dyes.
- 2. you have any other health problems or medical conditions, including:
- · kidney or liver problems
- nerve disease
- blood conditions.
- you are pregnant or plan to become pregnant.

Your doctor will discuss the risks and benefits of taking aciclovir when pregnant.

you are breast-feeding or wish to breastfeed.

Your doctor will discuss the risks and benefits of taking aciclovir when breastfeeding.

if you are taking, or about to take, any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Taking other medicines

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

Some medicines and aciclovir may interfere with each other. These include:

- probenecid, a medicine commonly used to treat gout.
- diuretics, also called fluid tablets.

These medicines may be affected by aciclovir, or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines. Your doctor will advise you.

Your doctor and pharmacist may have more information on medicines to be careful with or avoid while taking aciclovir.

Ask your doctor or pharmacist if you are not sure if you are taking any of these medicines.

How to take Aciclovir

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

They may differ from the information contained in this leaflet.

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

How to take it

The tablets should be swallowed whole with a full glass of water or dispersed in a quarter of a glass of water (about 50 mL) and then swallowed.

How much, when, and how long to take Aciclovir for

Take Aciclovir as directed by your doctor or pharmacist. Do not change the dose yourself.

Your doctor or pharmacist will tell you how many tablets you will need to take each day and when to take them. The dose will depend on what condition you are being treated for.

Take your medicine at about the same time each day.

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

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

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

To treat an outbreak of genital herpes, the usual dose of Aciclovir is one 200 mg tablet every four hours while awake (a total of 5 tablets daily) for 5 or 10 days after initial outbreak.

Start taking as advised by your doctor.

To prevent or reduce the number or outbreaks of herpes, the usual dose is one 200 mg tablet three times a day for up to 6 months.

Some people who have repeated outbreaks of herpes take Aciclovir for 5 days each time they have an outbreak. If this applies to you, it is important to start taking aciclovir at the first sign of an outbreak.

Keep taking Aciclovir until you finish the pack or for as long as your doctor recommends.

Do not stop taking Aciclovir, even if you feel better after a few days, unless advised by your doctor. Your herpes may not clear completely if you stop taking your tablets too soon.

Some patients will take a different dose to those described above. Your doctor will decide the right dose for you.

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

They may differ from the information contained in this leaflet.

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

If you forget to take it

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 the missed dose as soon as you remember, and then go back to taking your tablets as you would normally.

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

This may increase the chance of you getting an unwanted side effect.

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 pharmacist or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much aciclovir.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you take too many aciclovir tablets, you may feel or be sick, have a headache and/or feel confused

While you are taking Aciclovir

Things you must do

Drink plenty of fluids.

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

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

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking this medicine.

Tell your doctor immediately if you become pregnant.

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

Go to your doctor regularly for a check-up.

Your doctor may occasionally do a blood test to check your potassium levels and see how your kidneys are working.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

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

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

Things to be careful of

Genital herpes can be caught from, or spread to, your partner during sexual activity. It is important to remember that Aciclovir will not keep you from spreading herpes to others.

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

Side Effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. You may need medical treatment if you get some of the side effects.

Your doctor has weighed the risks of using this medicine against the benefits he/she expects it will have for you.

In a few people, aciclovir may have some unwanted side effects. Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Aciclovir. Often it is difficult to tell the difference between side effects of medicines and symptoms of the underlying illness

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

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

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

- 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
- skin reactions (e.g. rash. Itching, hives, overreaction to the sun)
- increased hair loss
- · weakness, fatigue, lack of energy, tiredness
- aching, leg pains, muscle pains, joint pain, muscle cramps
- menstrual problems.

The above list includes the more common side effects. Mostly, these are mild.

Tell your doctor immediately if you notice any of the following:

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

These may be serious side effects. You may need urgent medical attention. Serious side effects are mostly rare or very rare.

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

- yellowing of the skin and/or eyes (jaundice) or liver problems
- kidney problems or pain
- troubled breathing
- chest pain, fast heart beat
- convulsions (fits)
- signs of a serious allergic reaction such as shortness of breath, wheezing or troubled breathing, swelling of the face, lips, mouth, throat or tongue which may cause difficulty in swallowing or breathing, or swelling of other parts of the body
- swollen veins.

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

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

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

After taking Aciclovir

Storage

Keep your tablets in their original packaging until it is time to take them.

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

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

Do not store Aciclovir or any other medicine in the bathroom or near a sink.

Do not leave it on a window sill or in the car on hot days.

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 it has passed its expiry date, ask your pharmacist what to do with any that are left over.

Where to go for further information

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups and product specific organisations.

Product description

What it looks like

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

Packs of 90 tablets.

Ingredients

Active Ingredient:

Each tablet contains 200 mg of aciclovir.

Other Ingredients:

- lactose
- · magnesium stearate
- colloidal anhydrous silica
- croscarmellose sodium
- · microcrystalline cellulose
- indigo carmine.

This product does not contain sucrose, gluten, tartrazine or any other azo dyes.

Australian Registration Number

Aciclovir 200 Tablets: AUST R 130607.

Sponsor

Apotex Pty Ltd ABN 52 096 916 148 66 Waterloo Road North Ryde NSW 2113 Australia

Distributor

Pharmacor Limited

5/36 Campbell Ave Cromer, NSW 2099 Australia

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