

Acihexal[®]

aciclovir tablets

Consumer Medicine Information (CMI)

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Acihexal 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 Acihexal against the benefits it 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 want to read it again.

WHAT ACIHEXAL IS USED FOR

Acihexal is used for the treatment of genital herpes.

Acihexal is used for the treatment of shingles (herpes zoster). Shingles is caused by the same virus that causes chicken pox.

Acihexal is also used 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).

Acihexal 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 herpes viruses.

Your doctor may, however, have prescribed Acihexal for another reason.

If you have any questions about why you are taking Acihexal ask your doctor or pharmacist.

Acihexal contains the active ingredient aciclovir. Aciclovir belongs to a group of medicines called "anti-virals".

Acihexal works by stopping the multiplication of the virus that causes herpes. It can reduce the length and severity of an outbreak of herpes or alternatively may be used to reduce the number of outbreaks in someone who has frequent recurrences. It does not eliminate the herpes virus from the body.

BEFORE YOU TAKE ACIHEXAL

When you must not take it

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

- aciclovir, the active ingredient, or to any of the other ingredients listed at the end of this leaflet under Product Description
- any other similar medicines such as valaciclovir.

Do not take this medicine if you are pregnant.

It may affect your developing baby if you take it during pregnancy.

Do not breastfeed if you are taking this medicine.

The active ingredient in Acihexal passes into breast milk and there is a

possibility that your baby may be affected.

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.

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:

- a kidney or liver condition
- a blood condition, such as anaemia (a decreased red blood cell count) or neutropenia (lack of white blood cells)
- a disease affecting the nervous system
- any condition affecting your brain.

Tell your doctor if you plan on becoming pregnant or will be breastfeeding while you are using Acihexal.

Your doctor can 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 Acihexal.

Taking other medicines

Tell your doctor if you are taking any other medicine, including any

that you buy without a prescription from your pharmacy, supermarket or health food shop.

In particular, tell your doctor if you take the following:

- medicines such as probenecid or diuretics (fluid tablets)
- interferon, used to treat a range of conditions such as liver disease and some types of cancer
- intrathecal injections (which are injections into the space around the spinal cord) of methotrexate.

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

HOW TO TAKE ACIHEXAL

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, ask your doctor or pharmacist for help.

How much to take

The following is a guide to the usual dose:

Treatment of Genital Herpes

One Acihexal 200mg tablet five times a day, approximately every 4 hours throughout the day while awake. Either take your tablets at 7am, 11am, 3pm, 7pm, and 11pm or choose a timeframe that suits your daily schedule. Treatment should be for a period of 10 days.

To prevent or reduce the frequency of outbreaks in the long term, the usual dose is one Acihexal 200mg tablet three times daily for up to six months. Depending on the response your doctor may vary this dose.

Some people who have repeated outbreaks of herpes take one Acihexal 200mg tablet every four hours, a total of five tablets a day, for five days each time they have an outbreak. If this applies to you, it is important to start taking Acihexal at the first sign of an outbreak.

Treatment of Herpes Zoster (Shingles)

One Acihexal 800mg tablet five times a day, approximately every 4 hours throughout the day while awake. Either take your tablets at 7am, 11am, 3pm, 7pm, and 11pm or choose a timeframe that suits your daily schedule. Treatment should be for a period of 7 days. For herpes zoster ophthalmicus (herpes infection of the eyes) it is recommended that the duration of treatment is 7-10 days.

Treatment of HIV disease

If you have HIV the usual dose is one Acihexal 800mg tablet four times daily, every 6 hours. The treatment period is usually longer (12 months).

Do not stop taking Acihexal tablets because you feel better.

Do NOT take any more than prescribed by your doctor.

In all cases the duration of treatment will be determined by your doctor.

If you need to break Acihexal hold tablet with both hands and snap along break line.

If you forget to take it

If you have just missed your scheduled dose take it as soon as you remember, and continue to take it as you would normally.

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 are not sure what to do, ask your doctor or pharmacist.

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

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at your nearest hospital, if you think you or anyone else has taken too much Acihexal.

You may need urgent medical attention.

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

WHILE YOU ARE TAKING ACIHEXAL

Things you must do

Always follow your doctor's instructions carefully.

Tell your doctor if you become pregnant while taking Acihexal.

If you are about to start taking a new medicine, tell your doctor and pharmacist that you are taking Acihexal.

Drink plenty of fluids.

Things you must not do

Do not stop taking Acihexal without your doctor's permission. Do not stop taking Acihexal tablets because you feel better.

Do not use Acihexal to treat any other complaint unless your doctor says so.

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

Things to be careful of

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

SIDE EFFECTS

All medicines can have unwanted effects. Sometimes they are serious, most of the time they are not.

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

You may not experience any of them.

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

- nausea
- vomiting
- headache.

Other less frequently reported side effects are:

- diarrhoea, dizziness, tiredness, fever, fast heart rate
- weight loss, constipation, fluid retention, leg and joint pain
- taste disturbance, sore throat, skin rashes
- cramps, menstrual problems, hair loss
- irritability, swollen glands, vein disorders
- eye disorders, liver disorders
- confusion, sleep disturbances, shakiness, hallucinations.

These are the more common side effects of Acihexal. Mostly, these are mild and short-lived.

If any of the following happen, stop taking Acihexal, and tell your doctor immediately, or go to accident and emergency at your nearest hospital:

- swelling of the face, lips, mouth or throat, which may cause difficulty in swallowing or breathing.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

AFTER TAKING ACIHEXAL

Storage

Keep your medicine in the original container.

If you take it out of its original container it may not keep well.

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

Do not store Acihexal 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 if 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 it looks like

Acihexal 200mg tablets are white, round tablets with a break score on one side. They are available in blister packs of 25 or 90 tablets.

Acihexal 800mg tablets are white, biconvex oblong tablets with break scores on both sides. They are available in blister packs of 35 and 120 tablets.

Ingredients

Active Ingredients:

Each tablet of Acihexal 200mg contains 200mg aciclovir.

Each tablet of Acihexal 800mg contains 800mg aciclovir.

Inactive Ingredients:

- lactose
- microcrystalline cellulose
- sodium starch glycollate (type A)
- copovidone
- magnesium stearate

Supplier

Sandoz Pty Ltd

ABN 60 075 449 553

Level 2, 19 Harris Street

Pymont NSW 2009

Australia

Tel: 1800 634 500

Novartis New Zealand Ltd

Private Bag 65904 Mairangi Bay

Auckland 0754

New Zealand

Tel: 0800 354 335

This leaflet was revised in February 2012.

Australian Register Numbers

Acihexal 200mg tablets: AUST R 99420 (blisters)

Acihexal 800mg tablets: AUST R 99421 (blisters)