

Package leaflet: Information for the user

Aciclovir Accord 200 mg tablets
Aciclovir Accord 400 mg tablets
Aciclovir Accord 800 mg tablets
aciclovir

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Aciclovir Accord is and what it is used for
2. What you need to know before you take Aciclovir Accord
3. How to take Aciclovir Accord
4. Possible side effects
5. How to store Aciclovir Accord
6. Contents of the pack and other information

1. What Aciclovir Accord is and what it is used for

Aciclovir Accord contains the active substance aciclovir. Aciclovir belongs to a group of medicines called antivirals. It stops the growth of certain viruses.

Aciclovir Accord 200 mg and 400 mg can be used:

- to treat chickenpox and shingles; in shingles this medicine also helps to reduce nerve pain that may remain after the rash has disappeared;
- to treat cold sores, genital herpes and other infections caused by the herpes simplex virus;
- to prevent the recurrence of cold sores, genital herpes and other herpes simplex virus infections after you have had them;
- to prevent herpes simplex virus infections in people with a weakened immune system, who are less able to fight infections.

Aciclovir Accord 800 mg can be used:

- to treat shingles (herpes zoster);
- to treat chickenpox (varicella);
- to prevent shingles and chickenpox in people with a severely weakened immune system.

2. What you need to know before you take Aciclovir Accord

Do not take Aciclovir Accord

- if you are allergic to aciclovir, valaciclovir or any of the other ingredients of this medicine (listed in section 6).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking this medicine.

Warnings and precautions

Talk to your doctor before taking Aciclovir Accord if:

- you have kidney problems;
- you are over 65 years of age.

If any of the above apply to you, talk to your doctor. Your doctor may need to reduce your dose.

It is important to drink plenty of fluids while taking this medicine.

If you are not sure whether any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

Other medicines and Aciclovir Accord

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, especially:

- probenecid, used to treat gout;
- cimetidine, used to treat stomach ulcers;
- mycophenolate mofetil, used to prevent organ rejection after transplantation;
- valproate and phenytoin, used to treat epilepsy (seizures);
- theophylline, a medicine for diseases of the airways.

Pregnancy and breast-feeding

This medicine is not normally recommended during pregnancy. If you are pregnant, think you may be pregnant, are planning to have a baby or are breast-feeding, ask your doctor or pharmacist for advice before taking this medicine. Your doctor will weigh the benefits of treatment against the possible risks to your child.

The active substance of this medicine may pass into breast milk. If you are breast-feeding, ask your doctor for advice before using this medicine.

It is not known whether this medicine affects fertility in women.

Driving and using machines

Some side effects, such as drowsiness, may affect your ability to concentrate and react. Make sure you are not affected before driving or operating machinery.

Aciclovir Accord contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Aciclovir Accord

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you the correct dose for you, how to take this medicine and how long to take it, depending on:

- the type of infection;
- whether the infection is being treated or prevented from recurring.

The usual dose for the treatment of herpes simplex infections in adults is 200 mg, five times a day, with approximately 4 hours between doses. No dose is taken at night. Treatment usually lasts 5 days, but may be longer in severe infections.

Children aged 2 years and over usually receive the same dose as adults.

The usual dose to prevent recurrence of herpes simplex infections in adults is 200 mg, four times a day, with approximately 4 hours between doses. No dose is taken at night.

The usual dose for the treatment of chickenpox and shingles in adults is 800 mg, five times a day, with approximately 4 hours between doses. No dose is taken at night. Treatment usually lasts 7 days.

Children over 6 years usually receive 800 mg four times a day; children aged 2 to 6 years usually receive 400 mg four times a day; children under 2 years usually receive 200 mg four times a day.

If your kidneys do not work properly, your doctor will adjust your dose.

Taking this medicine

- Take this medicine by mouth.
- Swallow the tablets whole with plenty of water.
- Try to take this medicine at the same times each day.
- Take this medicine exactly as instructed by your doctor or pharmacist.
- Patients who have difficulty swallowing tablets may dissolve the tablets in at least 50 ml of water. Stir well before drinking.

If you take more Aciclovir Accord than you should

This medicine is not usually harmful unless large amounts are taken over several days. If you take too much, tell your doctor. Take the package with you.

If you forget to take Aciclovir Accord

If you forget to take a dose, take it as soon as you remember. If it is nearly time for the next dose, skip the missed dose.

Do not take a double dose to make up for a forgotten dose.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Serious side effects – seek medical help immediately

Severe allergic reactions (anaphylaxis) are rare (affecting fewer than 1 in 1,000 people).

Symptoms may include:

- itchy rash (hives);
- swelling of the lips, face, neck or throat causing difficulty breathing (angioedema);
- low blood pressure leading to fainting.

Stop taking this medicine and seek medical help immediately if you experience an allergic reaction.

Common side effects (may affect up to 1 in 10 people)

- headache;
- dizziness;
- nausea or vomiting;
- diarrhoea;
- stomach pain;
- itching;
- skin reaction after exposure to sunlight (photosensitivity);
- tiredness;
- fever.

Uncommon side effects (may affect up to 1 in 100 people)

- hives;
- hair loss.

Rare side effects (may affect up to 1 in 1,000 people)

- difficulty breathing;
- abnormal blood test results;
- angioedema;
- increased liver enzyme levels.

Very rare side effects (may affect up to 1 in 10,000 people)

- confusion or agitation;
- tremors;
- unsteady walking and lack of coordination (ataxia);
- slow or slurred speech;
- seeing or hearing things that are not there (hallucinations);

- psychotic disorders;
- epileptic seizures;
- drowsiness;
- brain disorder (encephalopathy);
- unconsciousness (coma);
- yellowing of the skin or eyes (jaundice), hepatitis;
- pain in the lower back or around the kidneys (kidney pain);
- reduced kidney function (kidney failure).

Very rare side effects detected in blood tests

- reduced red blood cells (anaemia);
- reduced white blood cells (leukopenia);
- reduced platelets (thrombocytopenia).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any side effects not listed in this leaflet. You can also report side effects via the Netherlands Pharmacovigilance Centre Lareb (www.lareb.nl). Reporting side effects helps provide more information on the safety of this medicine.

5. How to store Aciclovir Accord

- Keep this medicine out of the sight and reach of children.
- This medicine does not require any special storage conditions.
- Do not use this medicine after the expiry date stated on the package after EXP.

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. These measures help protect the environment.

6. Contents of the pack and other information

What Aciclovir Accord contains

- The active substance is aciclovir 200 mg, 400 mg or 800 mg per tablet.
- The other ingredients are microcrystalline cellulose (PH 101) (E460), sodium starch glycolate (Type A), povidone K25 (E1201), colloidal anhydrous silica, magnesium stearate (E470b).

What Aciclovir Accord looks like and contents of the pack

Aciclovir Accord tablets are supplied in PVC/aluminium blister packs.

Pack sizes:

- 200 mg: 25 and 30 tablets
- 400 mg: 25, 28, 30, 35 and 60 tablets
- 800 mg: 25, 30 or 35 tablets

Not all pack sizes may be marketed.

Tablet description:

- 200 mg: white to off-white, round tablets with bevelled edges, marked "LG1" on one side.
- 400 mg: white to off-white, round tablets with bevelled edges, scored, marked "LG" above the score and "2" below.
- 800 mg: white to off-white, oval, biconvex tablets, scored, marked "LG" and "3".

The score line is only to facilitate swallowing and not to divide the tablet into equal doses.

Marketing Authorisation Holder

Accord Healthcare B.V.
Winthontlaan 200
3526 KV Utrecht
The Netherlands

Manufacturer

Accord Healthcare Polska Sp. z o.o.
ul. Lutomska 50
95-200 Pabianice
Poland

Marketing Authorisation Numbers:

- Aciclovir Accord 200 mg tablets: RVG 128332
- Aciclovir Accord 400 mg tablets: RVG 128333
- Aciclovir Accord 800 mg tablets: RVG 128334

This medicine is authorised in the EEA under the following names:

Netherlands: Aciclovir Accord 200/400/800 mg tablets
Austria: Aciclovir Accord 200/400/800 mg Tablette
Latvia: Aciclovirum Accord 200/400/800 mg tablets
Lithuania: Aciclovirum Accord 200/400/800 mg tabletės
Bulgaria: Aciclovir Accord 400 mg tablets
Croatia: Aciklovir Accord 200/400 mg tablete
Poland: Aciclovir Accord

This leaflet was last approved in July 2024.