

Package leaflet: Information for the user

Acic 200 mg tablets Aciclovir

Read all of this leaflet carefully before taking this medication, as it contains important information for you.

- Keep this leaflet. You may need to read it again.
- Consult your doctor or pharmacist if you require any additional information or advice.
- This medication was prescribed to you personally. Do not give it to anyone else. The medication may harm them, even if they have similar symptoms.
- Consult your doctor or pharmacist if you experience any side effects. These may include some not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Acic 200 mg is and what it is used for
2. What you need to know before taking Acic 200 mg
3. How to take Acic 200 mg
4. Possible side effects
5. How to store Acic 200 mg
6. Contents of the pack and other information

1. What Acic 200 mg is and what it is used for

Acic 200 mg is an anti-herpes drug. Acic 200 mg contains the active substance acyclovir, which has a strong antiviral effect.

Herpes is a disease, which is caused by the *Herpes simplex* virus (HSV) and the *Varicella zoster* virus (VZV). Penetration of herpes-infected cells by acyclovir stops the virus from replicating, while having no effect on healthy cells.

2. What you need to know before taking Acic 200 mg

Do not take Acic 200 mg:

- if you are allergic (hypersensitive) to aciclovir, valaciclovir, or any of the ingredients of Acic 200.

Warnings and precautions

Special caution is advised:

- if you have immunodeficiency;
- if you have impaired kidney function or oliguria;
- if you are elderly;
- if your body is dehydrated.

Other medications and Acic 200 mg

Let your doctor or pharmacist know if you are using, have recently used, or are planning to use any other medications.

This mainly applies to the following medications:

- probenecid,
- mycophenolate mofetil,
- cimetidine.

It is, however, not necessary to change the dosing.

Acic 200 mg with food and drink

The tablets must be administered with a sufficient amount of fluid, preferably after meals.

Pregnancy, breast-feeding and fertility

Consult your doctor or pharmacist before using this medication if you are pregnant, breast-feeding, think you may be pregnant, or are planning to have a baby.

If treatment should prove necessary during pregnancy, the potential risk-benefit ratio of the treatment must be considered. Therapeutic doses of acyclovir are unlikely to be harmful to the foetus.

Acyclovir is excreted into breast milk, so breast-feeding during treatment with this medication is not recommended.

Driving and operating machinery

The effect of acyclovir on the ability to drive and operate machinery has not been studied. Based on the properties of the active ingredient, Acic 200 mg has no significant effect on the ability to drive and operate machinery. However, the symptoms and the effect of the disease must be considered and activities requiring attentiveness should be avoided, if necessary.

Acic 200 mg contains lactose

If your doctor has told you that you are intolerant to certain sugars, you must consult your doctor before using this medication.

Information for diabetics: 1 tablet contains less than 0.1 BU.

3. How to take Acic 200 mg

Always take this medication exactly in the way that was explained to you by your doctor. Consult your doctor or pharmacist if you are unsure of anything.

Adults

It is very important that treatment with acyclovir be started as quickly as possible – as soon as the first symptoms of the disease (pruritus, itchiness, and the first blisters) appear.

The medication is administered with regular 4, 6, or 12-hour intervals. The interval may be longer during nighttime.

Herpes simplex infections

200 mg of acyclovir (1 tablet of Acic 200 mg) 5 times daily every 4 hours.

Prophylaxis of severe and very often recurring Herpes simplex infections

In immunologically healthy patients, single doses of 200 mg (1 tablet of Acic 200 respectively) are administered 4 times daily every 6 hours. This can be replaced with administering 400 mg of acyclovir (2 tablets of Acic 200 respectively) twice daily with 12-hour intervals.

In individual cases, prophylaxis is also effective when 200 mg of acyclovir (1 tablet of Acic 200 respectively) is administered thrice daily every 8 hours or 200 mg of acyclovir (1 tablet of Acic 200 respectively) are administered twice daily every 12 hours.

If the infection recurs despite a total daily dose of 800 mg, 200 mg of acyclovir (1 tablet of Acic 200 mg) must be administered 5 times daily every 4 hours for five days – the same dosage that is used for treating *herpes simplex* infections.

Herpes zoster infections in immunocompetent patients are treated with 800 mg of acyclovir 5 times daily.

In immunocompromised patients, single doses of 200 mg of acyclovir (1 tablet of Acic 200 mg respectively) are administered 4 times daily every 6 hours for prophylaxis.

In patients with severe immunodeficiency, e.g. after undergoing organ transplantation, single doses of 400 mg of acyclovir (2 tablets of Acic 200 respectively) are administered 4 times daily every 6 hours. Development of resistance has been reported in immunocompromised patients. This must be taken into account when determining the dose.

In *Herpes simplex* infections in patients with severe immunodeficiency, severe primary genital herpes, and *herpes zoster* infections (especially in immunocompromised patients), as well as with potential drug metabolism disorders, injectable acyclovir should be used instead.

Children

Herpes simplex infections

Children over the age of 2 are given the adult dose; children under 2 are given half of the adult dose. The symptoms of infection with the *Herpes zoster infection* are typically milder in children than in adults. Nevertheless, 20 mg/kg, up to 800 mg 4 times daily for five days may be administered to children with a severe disease.

Dosing in the elderly

Potential kidney damage in the elderly must be considered and the dose should be adjusted accordingly (see below for dosing in the case of kidney damage).

Adequate fluid uptake must be ensured in elderly patients taking large oral doses of acyclovir.

Dosing in kidney damage

Care must be taken when administering acyclovir to patients with impaired renal function.

Adequate fluid uptake must be sustained.

When treating *Herpes simplex* in patients with severe kidney damage (creatinine clearance below 10 ml/min), it is recommended to adjust the dose to 200 mg of acyclovir twice daily with approximately 12-hour intervals.

When treating *Herpes zoster* in patients with severe kidney damage (creatinine clearance under 10 ml/min), it is recommended to adjust the dose to 800 mg of acyclovir twice daily with approximately 12-hour intervals. In patients with moderate kidney damage (creatinine clearance 10–25 ml/min), the recommended adjusted dose of acyclovir is 800 mg thrice daily with approximately 8-hour intervals.

Dose adjustment in adults and adolescents

<u>Creatinine clearance</u>	<u>Dosing</u>
25–50 ml/min	See recommended doses above (5 or 10 mg/kg of body weight), administered every 12 hours.
10–25 ml/min	See recommended doses above (5 or 10 mg/kg of body weight), administered every 24 hours.
0 (anuric)–10 ml/min	For patients undergoing continuous ambulatory peritoneal dialysis (CAPD), the doses recommended above (5 or 10 mg/kg of body weight) must be halved and administered every 24 hours. For patients undergoing haemodialysis, the doses recommended above (5 or 10 mg/kg of body weight) must be halved and administered every 24 hours after the dialysis.

Dose adjustment in infants and children

<u>Creatinine clearance</u>	<u>Dosing</u>
25–50 ml/min/1.73 m ²	Dose recommended above (250 or 500 mg/m ² body surface area or 20 mg/kg of body weight) must be administered every 12 hours.
10–25 ml/min/1.73 m ²	Dose recommended above (250 or 500 mg/m ² body surface area or 20 mg/kg of body weight) must be administered every 24 hours.
0 (anuric)–10 ml/min/1.73 m ²	For patients undergoing continuous ambulatory peritoneal dialysis (CAPD), the doses recommended above (250 or 500 mg/m ² body surface area or

20 mg/kg of body weight) must be halved and administered every 24 hours.

For patients undergoing haemodialysis, the doses recommended above (250 or 500 mg/m² body surface area or 20 mg/kg of body weight) must be halved and administered every 24 hours after the dialysis.

Mode of administration

The tablets must be administered with a sufficient amount of fluid, preferably after meals.

Duration of treatment

The duration of treatment for *Herpes simplex* infections is 5 days, but it may be extended depending on the condition of the patient.

The duration of prophylactic treatment for Herpes simplex infections in patients who have a normal immune response depends on the severity of the infection and the frequency of recurrences. However, the course of treatment must not be longer than 6–12 months.

The duration of prophylactic treatment for herpes simplex infections in severely immunodeficient patients depends on the degree of immunocompromise and the persistence of the risk of infection.

The duration of treatment for *Herpes zoster* is 5–7 days.

If you feel that the effect of Acic 200 mg is too strong or too weak, consult your doctor or pharmacist.

If you take more Acic 200 mg than you should

Taking up to 20 g acyclovir at once has normally not caused any signs of an overdose. Repeated oral administration of a dose that is several times larger than the recommended dose may cause nausea, vomiting, headaches, and confusion. If you suspect overdose or any side effects are exacerbated, please seek medical attention.

If you forget to take Acic 200 mg

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

If you stop taking Acic 200 mg

Consult your doctor or pharmacist if you have any further questions about using this medication.

4. Possible side effects

Like all medications, this medication can cause side effects, although not everyone experiences them.

Frequent (affect up to 1–10 in 100 people)

- headaches, dizziness
- nausea, vomiting, diarrhoea, abdominal pain
- itching, skin rash (incl. sensitivity to light)
- weakness, fever

Occasional (affect up to 1–10 in 1,000 people)

- urticaria, intensified hair loss (this is seen in several conditions and a causative link to treatment with acyclovir has not been established)

Rare (affect up to 1–10 in 10,000 people)

- anaphylaxis
- panting
- increased bilirubin concentration and liver enzyme activity
- angioedema (facial swelling)
- increased levels of urea and creatinine in the blood

Very rare (affect less than 1 in 10,000 people)

- anaemia (decreased number of red blood cells), leucopenia (decreased number of white blood cells), thrombocytopenia (decreased number of blood platelets)
- agitation, confusion, tremors, uncoordinated movements, speech impediments, hallucinations, psychotic symptoms, convulsions, drowsiness, encephalopathy (brain disease), coma
- hepatitis, icterus
- acute renal insufficiency, pain in the perirenal area (which may be connected to the renal insufficiency)

Reporting side effects

Consult your doctor or pharmacist if you experience any side effects. These may include some not mentioned in this leaflet.

5. How to store Acic 200 mg

Keep this medication out of the sight and reach of children.

Do not store at a temperature above 25 °C.

Do not use this medication after the expiration date which is marked on the box. The expiration date refers to the last day of that month.

Do not throw away any medications with wastewater or household waste. Ask your pharmacist how to dispose of medications you are no longer using. These measures will help to protect the environment.

6. Contents of the pack and other information

What Acic 200 mg contains

- The active ingredient is acyclovir. One tablet contains 200 mg of acyclovir.
- Other excipients are copolyvidone, lactose monohydrate, magnesium stearate, microcrystalline cellulose, sodium starch glycolate.

What Acic 200 mg looks like and contents of the pack

Acic 200 mg is a round tablet, 8.8–9.2 mm in diameter and 4–4.4 mm in length, with a score line on one side. The tablet can be divided into equal parts.

The original packaging contains 25 tablets.

Marketing Authorisation Holder and manufacturer

Marketing Authorisation Holder

Sandoz d.d.
Verovškova 57
1000 Ljubljana
Slovenia

Manufacturer

Salutas Pharma GmbH
Otto-von-Guericke-Allee 1
D-39179 Barleben
Germany.

This leaflet was last revised in July 2017.