

ACTI-VIR®
200 mg Tablets

Dear patient,

Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about ACTI-VIR

Each tablet of ACTI-VIR for oral use contains 200 mg acyclovir.

Acyclovir is a synthetic purine nucleoside analog antiviral agent active against herpes simplex virus type 1 and type 2 and against varicella-zoster virus.

Acyclovir exerts its antiviral effect against herpes simplex viruses (HSV) and varicella-zoster virus by interfering with DNA synthesis and inhibiting viral replication.

ACTI-VIR is indicated for the prevention and treatment of HSV infections and for the treatment of varicella-zoster infections in adults and children 6 years of age and older:

- Acute treatment of herpes zoster (shingles, zoster, zona): ACTI-VIR has a beneficial effect on pain and can reduce the incidence of post-herpetic neuralgia
- Treatment of initial episodes and the management of recurrent episodes of genital herpes
- Treatment of HSV mucocutaneous infections: esophageal, nasal and orolabial HSV infections, including gingivostomatitis
- Prevention of herpes simplex virus infections in immunocompetent patients suffering from recurrent HSV infections and in immunocompromised patients
- Prevention and treatment of ophthalmologic HSV infections
- Treatment of chickenpox (varicella)

The way to take ACTI-VIR

Take ACTI-VIR as directed by your physician. Do not discontinue the treatment without consulting your doctor.

Dosage and duration of treatment are individualized on the basis of the condition under treatment.

ACTI-VIR may be administered without regard to meals.

The usual recommended dosages are:

Indication	Dosage
Acute treatment of Herpes Zoster	800 mg (4 tablets of 200 mg) every 4 hours 5 times daily for 7-10 days
Treatment of HSV mucocutaneous infections (e.g., labial)	200 mg (1 tablet) every 4 hours while awake (5 times daily) for 5-10 days
Treatment of ocular HSV infections	400 mg (2 tablets of 200 mg) every 4 hours while awake (5 times daily)
Genital Herpes	<i>Initial Genital Herpes:</i> 200 mg (1 tablet) every 4 hours while awake, (5 times daily) for 10 days <i>Chronic suppressive therapy for recurrent disease:</i> 400 mg (2 tablets of 200 mg) 2 times daily for up to 12 months, followed by reevaluation. Alternative regimens: 200 mg 3 to 5 times daily. <i>Intermittent therapy:</i> 200 mg (1 tablet) every 4 hours, 5 times daily for 5 days. Therapy should be initiated at the earliest sign or symptom of recurrence.
Prevention of HSV infections	400 mg twice daily (2 tablets of 200 mg twice daily). Treatment should be evaluated every 6 to 12 months.
Chickenpox (Varicella)	<i>Children 6 years of age and older less than 40 kg:</i> 20 mg/kg/dose 4 times daily for 5 days <i>Adults and children over 40 kg:</i> 800 mg (4 tablets of 200 mg) 4 times daily for 5 days

Other dosages may be recommended in some cases.

The usual adult dosages are generally recommended for the treatment of herpes simplex infections and for the prophylaxis of HSV infections in children over the age of 6 years.

In case of overdose

In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

This drug is contraindicated for patients who develop hypersensitivity to acyclovir or valacyclovir.

Precautions

- Dosage adjustment is recommended when administering this drug to patients with renal impairment.
- Treatment should be initiated as soon as possible after a diagnosis of herpes zoster or chickenpox.
- Inform your doctor before using this medication in case of pregnancy or lactation. Limited data are available on the use of acyclovir during pregnancy. This drug should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

This drug should be used with caution in patients receiving nephrotoxic drugs or probenecid concurrently.

Adverse reactions

This drug is generally well tolerated. The most reported adverse reactions include: headache, fatigue, rash, nausea, vomiting and diarrhea. Dizziness, elevated liver function test results, and hyperbilirubinemia have been rarely reported.

Inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (up to 25°C), protected from light and humidity, beyond the reach of children.

The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

ACTI-VIR, acyclovir 200 mg, pack of 25 tablets

Revision date: 06/2008

ACVT2/002