

Acyclovir Tablets USP

AVIR-200/400

POM

COMPOSITION:

AVIR-200

Each uncoated tablet contains:
Acyclovir USP 200 mg
Excipients Q.S.

AVIR-400

Each uncoated tablet contains:
Acyclovir USP 400 mg
Excipients Q.S.

THERAPEUTIC CLASS:

Antiviral Drug

PHARMACOLOGICAL ACTIONS:

Acyclovir after intracellular uptake, converted to acyclovir monophosphate by virally-encoded thymidine kinase, which is then phosphorylated after entering into the herpes infected cells to the active acyclovir triphosphate compound. The acyclovir triphosphate inhibits viral DNA polymerase and thereby inhibits viral DNA synthesis and replication. This process takes place without affecting the normal cellular processes. Acyclovir triphosphate is active in vitro against type I and II herpes simplex and Varicella zoster viruses.

Pharmacokinetics:

Absorption: Acyclovir can be given orally, intravenously or topically. When it is given orally, only 20% of the dose is absorbed and peak plasma concentrations are reached in 1-2 hours.

Distribution: The drug is widely distributed, reaching concentrations in the CSF that are 50% of those in the plasma.

Excretion: It is excreted by the kidneys, partly by glomerular filtration and partly by tubular secretion.

INDICATIONS:

- Treatment of initial and recurrent Herpes simplex infections of the skin and mucous membranes including initial and recurrent genital Herpes simplex infections.
- Suppression of recurrent genital Herpes simplex infections in immunocompetent patients.
- Prophylaxis of Herpes simplex infections in immunocompromised patients.
- Treatment of Herpes zoster infections if the lesions are not older than 72 hours.
- Treatment of Varicella zoster (chickenpox) within 24 hours after appearance of the typical chickenpox rash.

CONTRAINDICATIONS:

Acyclovir tablet is contraindicated in patients known to be hypersensitive to acyclovir. The safety of acyclovir in pregnancy has not been established. Acyclovir should not be administered to pregnant women or nursing women as acyclovir passes into breast milk.

ADVERSE EFFECTS:

Effects on skin: Skin rashes which disappear after withdrawal of medication.

Effects on gastro-intestinal tract: Nausea, vomiting, diarrhoea and vomiting.

Other reactions: Reversible neurological reactions, dizziness, hallucinations and somnolence especially in patients with renal impairment. Rises in bilirubin and liver related enzymes, elevations in blood and creatinine; minimal decreases in haematological indices, headaches and fatigue. Accelerated diffuse hair loss has also been reported. Patients with a suppressed immune response may be particularly prone to acyclovir-resistant mucocutaneous herpes simplex infections. Resistance has also been reported with Varicella-zoster virus.

WARNINGS & PRECAUTIONS:

Acyclovir should be administered with caution to patients with renal impairment and doses should be adjusted according to creatinine clearance. The risk of renal impairment is increased by the concomitant use of other nephrotoxic agents.

DOSAGE & ADMINISTRATION:

Dosage in Adults

For treatment of initial and recurrent Herpes simplex infections of the skin and mucous membranes:

- 200 mg acyclovir should be taken 5 times per day at approximately four hourly intervals omitting the night time dose. Treatment should continue for 5 days, but in a case of severe initial infection the treatment period may have to be extended.
- In severely immune-compromised patients e.g. after marrow transplant or in patients with impaired absorption from the gut the dose can be doubled to 400 mg or, alternatively, intravenous dosing could be considered.

- The first dose should be administered as early as possible after the start of an infection and for recurrent episodes this should preferably be during the prodromal period or when lesions first appear.

For suppression of recurrent genital Herpes simplex infections in immunocompetent adults:

- A dose of 200 mg of acyclovir should be taken four times daily at approximately six-hourly intervals.
- Many patients may be conveniently managed on a regimen of 400 mg of oral acyclovir taken twice daily at approximately twelve-hourly intervals. Dosage titration down to 200 mg oral acyclovir taken at approximately eight-hourly intervals or even twice daily at approximately twelve-hourly intervals may prove effective. Some patients may experience break-through infections on total doses of 800 mg acyclovir.
- Therapy should be interrupted periodically at intervals of six to twelve months, in order to observe possible changes in the natural history of the disease.

For prophylaxis of Herpes simplex infections in immunocompromised adults:

- 200 mg Acyclovir should be taken four times daily at approximately six hourly intervals. In severely immunocompromised patients (e.g. after marrow transplant) or in patients with impaired absorption from the gut the dose can be doubled to 400 mg, or alternatively intravenous dosing could be considered. The duration of prophylactic administration is determined by the duration of the period at risk.

For treatment of Varicella zoster infections in adolescents (12 to 18 years):

- A dose of 800 mg oral acyclovir should be taken four times daily for five days.

For treatment of Varicella zoster and Herpes zoster infections in adults:

- A dose of 800 mg oral acyclovir should be taken five times daily at approximately four-hourly intervals, omitting the night-time dose. Treatment should continue for 7 days.
- In severely immunocompromised patients (e.g. after marrow transplant) or in patients with impaired absorption from the gut, consideration should be given to intravenous dosing.
- Dosing should begin as early as possible after the start of an infection: treatment yields better results if initiated as soon as possible after rash onset.

Dosage in the Elderly:

- In the elderly total acyclovir body clearance declines, thus adequate hydration should be maintained. Special attention should be given to dosage reduction in elderly patients with impaired renal function.

Dosage in Renal Impairment:

Dosage should be reduced in renal failure. The following is recommended:

Normal dose regimen	Creatinine Clearance (mL/min/1.73 m ²)	Adjusted Dosage Regimen	
		Dose (mg)	Dosing interval
200 mg every four hours for herpes simplex infections	0 - 10	200	every 12 hours,
800 mg every four hours for Varicella zoster infections	>25	800	every 4 hours
	10-25	800	every 8 hours
	0-10	800	every 12 hours

Patients on haemodialysis should receive their usual appropriate daily dosage after each dialysis.

OVERDOSAGE:

Acyclovir is removed by haemodialysis. Treatment is symptomatic and supportive, although no data is available on the effects after ingestion of high doses.

DRUG INTERACTIONS:

Probenecid blocks the renal clearance of acyclovir and thus increases the mean half life. The risk of renal impairment is increased by the concomitant use of nephrotoxic medicine.

PRESENTATION:

Blister pack

STORAGE CONDITION:

Store below 30°C. Protect from light.

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