

Simplovir™

Aciclovir

Presentation

- Simplovir™ 200 tablet: Each tablet contains Aciclovir BP 200 mg.
- Simplovir™ 400 tablet: Each tablet contains Aciclovir BP 400 mg.
- Simplovir™ 250 IV: Each vial contains lyophilized powder of Aciclovir Sodium equivalent to Aciclovir BP 250 mg.
- Simplovir™ 500 IV: Each vial contains lyophilized powder of Aciclovir Sodium equivalent to Aciclovir BP 500 mg.
- Simplovir™ 1 gm IV: Each vial contains lyophilized powder of Aciclovir Sodium equivalent to Aciclovir BP 1 gm.
- Simplovir™ Suspension: Each 5 ml suspension contains Aciclovir BP 200 mg.

Description

Simplovir is the brand name of Aciclovir, a synthetic purine nucleoside with inhibitory activity against herpes simplex virus (HSV-1 & HSV-2) and varicella-zoster virus (VZV). The activity of Aciclovir is highly selective due to its affinity for the enzyme thymidine kinase encoded by HSV and VZV. This viral enzyme converts Aciclovir into Aciclovir monophosphate, a nucleotide analogue. The monophosphate is further converted into diphosphate and finally triphosphate by a number of cellular enzymes. In vitro, Aciclovir triphosphate stops replication of herpes viral DNA. This is accomplished in 3 ways: 1) Competitive inhibition of viral DNA polymerase, 2) Incorporation into and termination of the growing viral DNA chain and 3) Inactivation of the viral DNA polymerase.

Indications

- Herpes Zoster
- Genital Herpes
- Chickenpox
- Herpes Simplex Infections
- Herpes Simplex Encephalitis

Dosage and administration

The total daily dosage of Aciclovir should be based on the type or severity of infection and given in equally divided doses based on consideration of degree of susceptibility of the pathogens, renal function and body-weight.

Simplovir Tablet & Oral Suspension

- **Acute Herpes Zoster:** 800 mg or 20 ml suspension every 4 hours, 5 times daily for 7 to 10 days.
- **Genital Herpes:** Initial Genital Herpes: 200 mg or 5 ml suspension every 4 hours, 5 times daily for 10 days.
Chronic suppressive therapy for recurrent disease: 400 mg or 10 ml suspension 2 times daily for up to 12 months.
Intermittent therapy: 200 mg or 5 ml suspension every 4 hours, 5 times daily for 5 days.
- **Chickenpox:** Children (2 years of age and older): 20 mg/kg/dose 4 times daily (80 mg/kg/day) for 5 days.
Adults and Children (>40 kg): 800 mg or 20 ml suspension 4 times daily for 5 days.

Simplovir IV

The required dose of Aciclovir IV should be administered by slow intravenous infusion over a one-hour period.

- **Herpes Simplex (HSV-1 and HSV-2) Infections:** Adults and Adolescents (≥12 years): 5 mg/kg, 8 hourly for 7 days.
Pediatrics (<12 years): 10 mg/kg 8 hourly for 7 days.
- **Severe Initial Herpes Genitalis:** Adults and Adolescents (≥12 years): 5 mg/kg 8 hourly for 5 days.
- **Herpes Simplex Encephalitis:** Adults and Adolescents (≥12 years): 10 mg/kg 8 hourly for 10 days.
Pediatrics (3 months to 12 years of age): 20 mg/kg 8 hourly for 10 days.
- **Neonatal Herpes Simplex (Birth to 3 months):** 10 mg/kg 8 hourly for 10 days.
- **Varicella Zoster:** Adults and Adolescents (≥12 years): 10 mg/kg 8 hourly for 7 days.
Pediatrics (<12 years): 20 mg/kg 8 hourly for 7 days.

Patients with acute or chronic renal impairment

Table 1. Dose adjustment of Tablet

Normal Dosage Regimen	Creatinine Clearance (mL/min/1.73 m ²)	Adjusted Dosage Regimen	
		Dose (mg)	Dosing Interval
200 mg every 4 hours	>10	200	4 hourly, 5x daily
	0-10	200	12 hourly
400 mg every 12 hours	>10	400	12 hourly
	0-10	200	12 hourly
800 mg every 4 hours	>25	800	4 hourly, 5x daily
	10-25	800	8 hourly
	0-10	800	12 hourly

Table 2. Dose adjustment of IV

Creatinine Clearance (mL/min/1.73 m ²)	Percent of Recommended Dose	Dosing Interval (hours)
>50	100%	8
25 - 50	100%	12
10 - 25	100%	24
0 - 10	50%	24

Caution: Rapid or bolus intravenous injection must be avoided. Intramuscular or subcutaneous injection must be avoided.

Reconstitution procedure of IV infusion

Vial containing 250 mg Aciclovir will be reconstituted with 50 ml infusion solution and vial containing 500 mg Aciclovir will be reconstituted with 100 ml infusion solution. Besides, Vial containing 1 gm Aciclovir will be reconstituted with 250 ml infusion solution, 10 ml of the infusion solution will be added to the vial containing 250 mg, 500 mg and 1 gm Aciclovir. Shake well and transfer the required amount of solution to the infusion container. The final concentration of Aciclovir will be not more than 5 mg/ml. The reconstituted solution should be used within 12 hours. Refrigeration of reconstituted solution may result in the formation of a precipitate which will re-dissolve at room temperature.

Compatible infusion fluids

- Sodium Chloride Intravenous Infusion BP (0.45% and 0.9% w/v)
- Sodium Chloride (0.18% w/v) and Glucose (4% w/v) Intravenous Infusion BP
- Sodium Chloride (0.45% w/v) and Glucose (2.5% w/v) Intravenous Infusion BP
- Hartmann's Solution

Contraindication

Aciclovir is contraindicated in patients known to be hypersensitive to Aciclovir or Valaciclovir.

Precaution

Aciclovir should be administered with caution in patient with renal impairment and doses should be adjusted according to creatinine clearance.

Use in pregnancy & lactation

Pregnancy category B & caution should be exercised when it is administered to a lactating mother.

Drug interaction

Probenecid reduces Aciclovir excretion and so increases plasma concentration and risk of toxicity.

Side effect

Rash, gastro-intestinal disturbances, rises in bilirubin and liver-related enzymes, increase in blood urea and creatinine, decreases in hematological indices, headache, neurological reactions, fatigue.


Storage

Do not store above 30° C. Keep out of the reach of children.

Commercial pack

- Simplovir™ 200 mg tablet: Each box contains 3 blister strips of 10 tablets.
- Simplovir™ 400 mg tablet: Each box contains 2 blister strips of 10 tablets.
- Simplovir™ 250 IV: Each box contains 1 vial of 250 mg Aciclovir lyophilized powder, 1 bottle of 50 ml of 0.9% Sodium Chloride solution, 1 disposable syringe & 1 infusion set.
- Simplovir™ 500 IV: Each box contains 1 vial of 500 mg Aciclovir lyophilized powder, 1 bottle of 100 ml of 0.9% Sodium Chloride solution, 1 disposable syringe & 1 infusion set.
- Simplovir™ 1 gm IV: Each box contains 1 vial of 1 gm Aciclovir lyophilized powder, 1 bottle of 250 ml of 0.9% Sodium Chloride solution, 1 disposable syringe & 1 infusion set.
- Simplovir™ Suspension: Each box contains 70 ml suspension in PET bottle and a measuring cup.

Manufactured by

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