

Alaclov®

Valaciclovir

Description

Alaclov® is a preparation of Valaciclovir which is an antiviral agent. It is a prodrug, converted by esterases to the active drug Aciclovir, as well as the amino acid valine, via hepatic first-pass metabolism.

Indications

Alaclov® is indicated for treatment of -

- Herpes zoster (Shingles)
- Initial and suppression of recurrent herpes simplex infections of skin & mucous membrane including initial and recurrent genital herpes
- Reduction of transmission of genital herpes
- Prevention of cytomegalovirus disease following organ transplantation
- Cold sores (Herpes labialis or fever blisters)

Dosage and administration

Adult

- Herpes zoster: 1 gm three times daily for 7 days.
- Herpes simplex:
 - First episode, 500 mg twice daily for 5 days, longer if new lesions appear during treatment or if healing incomplete (1 gm twice daily for 10 days for genital herpes in immunocompromised or HIV positive patients).
 - Recurrent infection, 500 mg twice daily for 5 days (1 gm twice daily for 5 to 10 days for genital herpes in immunocompromised or HIV positive patients).
 - Herpes simplex, suppression, 500 mg daily in 1 to 2 divided doses (in immunocompromised or HIV positive patients, 500 mg twice daily).
- Reduction of transmission of genital herpes, 500 mg once daily to be taken by the infected partner.
- Prevention of cytomegalovirus disease following renal transplantation (preferably starting within 72 hours of transplantation), 2 gm four times daily usually for 90 days.

Children

Children 12 to 18 years of age

- Herpes zoster: In immunocompromised patients, 1 gm three times daily for 7 days.
- Herpes simplex:
 - First episode, 500 mg twice daily for 5 days (longer if new lesions appear during treatment or if healing incomplete)
 - Recurrent infection, 500 mg twice daily for 5 days
 - Suppression of Herpes simplex, 500 mg daily in 1 to 2 divided doses (in immunocompromised or HIV positive patients, 500 mg twice daily)
- Prevention of cytomegalovirus disease following renal transplantation (preferably starting within 72 hours of transplantation): 2 gm four times daily usually for 90 days.
- Cold Sores (Herpes labialis): The recommended dose is 2 gm twice daily for 1 day taken 12 hours apart.

Children 02 to 18 years of age

- Chickenpox: The recommended dosage for chickenpox in immunocompetent pediatric patient is 20 mg/kg administered three times daily for 5 days. The total dose should not exceed 1 gm three times daily.

Therapy should be initiated at the earliest symptom.

Patients with Renal Impairment

Dosage recommendations for adult patients with reduced renal function are given below.

Indications	Normal Dosage Regimen (Creatinine Clearance ≥ 50 mL/min)	Creatinine Clearance (mL/min)		
		30-49	10-29	< 10
Herpes zoster	1 gm every 8 hours	1 gm every 12 hours	1 gm every 24 hours	500 mg every 24 hours
Genital herpes: Initial episode	1 gm every 12 hours	No reduction	1 gm every 24 hours	500 mg every 24 hours
Genital herpes: Recurrent episode	500 mg every 12 hours	No reduction	500 mg every 24 hours	500 mg every 24 hours
Immunocompetent patients	1 gm every 24 hours	No reduction	500 mg every 24 hours	500 mg every 24 hours
Alternate dose for immunocompetent patients with ≤ 9 recurrences/year	500 mg every 24 hours	No reduction	500 mg every 48 hours	500 mg every 48 hours
HIV-infected patients	500 mg every 12 hours	No reduction	500 mg every 24 hours	500 mg every 24 hours
Cold sores (Herpes labialis) Do not exceed 1 day of treatment.	Two 2 gm doses taken 12 hours apart	Two 1 gm doses taken 12 hours apart	Two 500 mg doses taken 12 hours apart	500 mg single dose

Data are not available for the use of valaciclovir in pediatric patients with a creatinine clearance < 50 mL/min/1.73 m².

Pregnancy and lactation

Valaciclovir is in pregnancy category B. It should be used during pregnancy & lactation only if the potential benefit justifies the risk.

Side-effects

Valaciclovir is generally well tolerated. The common side effects are nausea, vomiting, fatigue, headache, dizziness, stomach pain, agitation, hallucinations, confusion, speech problems, unsteady movement, vision changes, seizures, loss of consciousness & fever.

Contraindications

Valaciclovir is contraindicated in patients with clinically significant hypersensitivity reaction to Valaciclovir, Aciclovir, or any component of the formulation.

Precautions

Dosage reduction should be recommended when administering Valaciclovir to patients with renal impairment. The safety & efficacy of Valaciclovir have not been established in immuno-

compromised patients other than for the suppression of genital herpes in HIV infected patients. Caution should be taken in patients with hepatic impairment & blood disorders.

Overdose

Acute renal failure & neurological symptoms, including confusion, hallucinations, agitation, decreased consciousness & coma, have been reported in patients receiving overdoses of Valaciclovir. Caution is required to prevent inadvertent overdosing. Haemodialysis significantly enhances the removal of Aciclovir from the blood and may, therefore, be considered a management option in the event of symptomatic overdose.

Drug interactions

No clinically significant drug-drug interactions with Valaciclovir are known. No dosage adjustment is recommended when valaciclovir is co-administered with digoxin, antacids, thiazide diuretics, cimetidine or probenecid in subjects with normal renal functions.

Pharmaceutical precautions

Store at room temperature, away from light and moisture. Keep all medicines away from children and pets.

Presentation

Alaclov[®] 10 tablet: Each tablet contains Valaciclovir 500 mg

Package quantities

Alaclov[®] 10 tablet: Carton of 10 tablets in Alu-PVC blister

[®] Registered Trade Mark



ACI Limited

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