

Revira™

Valaciclovir INN

COMPOSITION: Revira™ 500: Each film coated tablet contains Valaciclovir HCl INN equivalent to 500 mg Valaciclovir. **Revira™ 1 gm:** Each film coated tablet contains Valaciclovir HCl INN equivalent to 1 gm Valaciclovir.

PHARMACOLOGY: Valaciclovir is an antiviral drug. After oral administration, Valaciclovir hydrochloride is rapidly absorbed from the gastrointestinal tract and nearly completely converted to Aciclovir and L-valine by first-pass intestinal and/or hepatic metabolism. Valaciclovir is a nucleoside analogue DNA polymerase inhibitor. Valaciclovir hydrochloride demonstrates antiviral activity against Herpes Simplex Virus type 1 (HSV-1) and type 2 (HSV-2) and Varicella Zoster Virus (VZV).

INDICATION: Adult Patients:

- Cold Sores (Herpes Labialis)
- Genital Herpes
- Initial episodes ■ Treatment of recurrent episodes in immunocompetent patients ■ Chronic suppressive therapy of recurrent episodes in immunocompetent or HIV- infected patients ■ Reduction of transmission of genital herpes

- Herpes zoster (shingles).

Pediatric Patients:

- Cold Sores (Herpes Labialis)
- Chickenpox.

DOSAGE AND ADMINISTRATION:

Adult	
Cold Sores (Herpes Labialis)	2 gm every 12 hours for 1 day
Genital Herpes	
■ Initial episode	1 gm twice daily for 10 days
■ Recurrent episodes	500 mg twice daily for 3 days
■ Suppressive therapy	
• Immunocompetent patients	1 gm once daily
• Alternate dose (in patients with ≤9 recurrences/yr)	500 mg once daily
• HIV-infected patients	500 mg twice daily
■ Reduction of transmission	500 mg once daily
Herpes Zoster	1 gm 3 times daily for 7 days
Pediatric	
Cold Sores (≥12 years of age)	2 gm twice daily for 1 day
Chickenpox (2 to <18 years of age)	20 mg/kg 3 times daily for 5 days (not to exceed 1 gm 3 times daily)

CONTRAINDICATION: Valaciclovir is contraindicated in patients who are hypersensitive to Valaciclovir, Aciclovir, or any component of the formulation.

PRECAUTION: Dosage reduction is recommended when administering Valaciclovir to patients with renal impairment. Similar caution should be exercised when administering to geriatric patients and patients receiving potentially nephrotoxic agents.

ADVERSE REACTION: The most common side effects are headache, nausea, and abdominal pain. The only adverse reaction reported in pediatric patients < 18 years of age was headache. Other infrequent side effects include facial edema, hypertension, tachycardia, acute hypersensitivity reactions, agitation, ataxia, coma, confusion, decreased consciousness, dysarthria, encephalopathy, seizures, tremors, visual abnormalities, diarrhea, liver enzyme abnormalities, hepatitis, renal failure or pain, thrombocytopenia, rashes etc.

DRUG INTERACTION: No clinically significant drug-drug or drug-food 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 function.

USE IN PREGNANCY AND LACTATION: *Pregnancy:* Pregnancy Category B. There are no adequate and well-controlled studies of Valaciclovir or Aciclovir in pregnant women. Valaciclovir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. *Nursing Mothers:* Valaciclovir should be administered to a nursing mother with caution and only when indicated.

PEDIATRIC USE: Valaciclovir is indicated for treatment of cold sores in pediatric patients 12 years of age and for treatment of chickenpox in pediatric patients 2 to < 18 years of age.

GERIATRIC USE: Elderly patients are more likely to have reduced renal function and require dose reduction. They are also more likely to have renal or CNS adverse events. So caution should be exercised when Valaciclovir is administered to elderly patients.

STORAGE CONDITION: Store in a dry and cool place. Protect from light and moisture. Keep the medicine out of the reach of children.

HOW SUPPLIED: Revira™ 500 Tablet: Each box contains 10 tablets in Alu-Alu blister pack.

Revira™ 1 gm Tablet: Each box contains 12 tablets in Alu-Alu blister pack.

Manufactured by :



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PHARMACEUTICALS LTD.
BANGLADESH

TM - Trade Mark.