

Revira[®]

Valaciclovir INN

DESCRIPTION

Valaciclovir (as hydrochloride) is the hydrochloride salt of L-valyl ester of the antiviral drug Aciclovir.

PRESENTATION

Revira[®] tablet: Each film coated tablet contains Valaciclovir HCl INN equivalent to 500 mg Valaciclovir.

INDICATION

Herpes Zoster: **Revira[®]** is indicated for the treatment of herpes zoster (shingles).

Genital Herpes: **Revira[®]** is indicated for the treatment or suppression of genital herpes in immunocompetent individuals and for the suppression of recurrent genital herpes in HIV-infected individuals.

Cold Sores (Herpes Labialis): **Revira[®]** is indicated for the treatment of cold sores (herpes labialis).

DOSAGE AND ADMINISTRATION

Revira[®] tablets may be given without regard to meals.

Herpes Zoster: The recommended dosage for the treatment of herpes zoster is 1 gram orally 3 times daily for 7 days. Therapy should be initiated at the earliest sign or symptom of herpes zoster and is most effective when started within 48 hours of the onset of zoster rash.

Genital Herpes: *Initial Episodes:* The recommended dosage for treatment of initial genital herpes is 1 gram twice daily for 10 days. *Recurrent Episodes:* The recommended dosage for the treatment of recurrent genital herpes is 500 mg twice daily for 3 days. *Suppressive Therapy:* The recommended dosage for chronic suppressive therapy of recurrent genital herpes is 1 gram once daily in patients with normal immune function. In patients with a history of 9 or fewer recurrences per year, an alternative dose is 500 mg once daily.

In HIV-infected patients with CD₄ cell count >100 cells/mm³, the recommended dosage for chronic suppressive therapy of recurrent genital herpes is 500 mg twice daily. *Reduction of Transmission:* The recommended dosage for reduction of transmission of genital herpes in patients with a history of 9 or fewer recurrences per year is 500 mg once daily for the source partner.

Cold Sores (Herpes Labialis): The recommended dosage for the treatment of cold sores is 2 grams twice daily for 1 day taken about 12 hours apart.

Patients with Acute or Chronic Renal Impairment: In patients with reduced renal function, reduction in dosage is recommended.

CONTRAINDICATION

Valaciclovir is contraindicated in patients with a known hypersensitivity or intolerance 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. The safety and efficacy of Valaciclovir have not been established in immunocompromised patients other than for the suppression of genital herpes in HIV-infected patients.

ADVERSE REACTION

Nausea, headache, vomiting, dizziness and abdominal pain may occur. In rare cases following adverse reactions reported:

General: Facial edema, hypertension, tachycardia.

Allergic: Acute hypersensitivity reactions including anaphylaxis, angioedema, dyspnea, pruritus, rash, and urticaria.

CNS Symptoms: Aggressive behavior; agitation; ataxia; coma; confusion; decreased consciousness; dysarthria; encephalopathy; mania; and psychosis, including auditory and visual hallucinations; seizures, tremors.

Eye: Visual abnormalities.

Gastrointestinal: Diarrhea.

Hepatobiliary Tract and Pancreas: Liver enzyme abnormalities, hepatitis.

Renal: Elevated creatinine, renal failure.

Hematologic: Thrombocytopenia, aplastic anemia, leukocytoclastic vasculitis, TTP/HUS.

DRUG INTERACTION

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

Safety and effectiveness of Valaciclovir in pre-pubertal pediatric patients have not been established.

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[®] tablet: Each box contains 1x10 tablets in Alu-Alu blister pack.

Manufactured by



SQUARE
PHARMACEUTICALS LTD.
BANGLADESH