

Composition

Each 5 ml contains Acyclovir 200 mg

Action

Acyclovir is an antiviral agent with activity against Herpes simplex virus types 1 and 2, (HSV-1 and HSV-2) and varicella zoster virus (VZV). Acyclovir is phosphorylated after entry into herpes infected cells to the active compound acyclovir triphosphate. The first step in this process is dependent on the presence of the HSV coded thymidine kinase. Thymidine kinase converts acyclovir into acyclovir monophosphate. The monophosphate is converted to diphosphate by cellular guanylate kinase and to triphosphate, which is the active form of the medicine. Acyclovir triphosphate interferes with HSV and VZV DNA polymerase and inhibits viral DNA replication.

Clinical uses of Acyclovir

Virax indicated in the treatment of the following infections due to the following organisms:

- *Herpes Simplex* virus (types 1 and 2).
- *Varicella Zoster* virus (Herpes Zoster and Chickenpox).
- Herpes Simplex infections including *Herpes Keratitis*, *Herpes Labialis* and Genital Herpes respond to Acyclovir given by intravenous, oral or topical routes as soon as possible after symptoms appear.
- Both initial and recurrent infections can be successfully treated.

Prolonged treatment can reduce the incidence of recurrence that is important in immunocompromised patients. However, when prolonged treatment is withdrawn infections may recur. Virax also improves for healing of Herpes Zoster lesions when given intravenously or by oral route, although studies indicate that it has little effect on pain.

Pharmacokinetics

When given orally, 15-30% of acyclovir is absorbed from the gastrointestinal tract. The absorption of acyclovir is not significantly altered when administered after a meal. The mean steady-state peak concentrations after repeated oral administration of acyclovir 200 mg is 0,6 mcg/ml.

Acyclovir is bound to plasma proteins up to an extent of 9 to 33%.

Acyclovir is predominantly eliminated unchanged by glomerular filtration and tubular secretion. The terminal elimination half-life of acyclovir is about 2-3 hours in subjects with normal renal function; this may increase to 20 hours in patients with severely compromised renal function. About 15% of the administered dose is recovered in the urine as an inactive metabolite (9-carboxy methoxy methyl guanine) and about 2% is excreted with the faeces.

Indications

- Herpes Zoster Infections: Virax indicated for the acute treatment of herpes zoster (shingles).
- Genital Herpes: Virax indicated for the treatment of initial episodes and the management of recurrent episodes of genital herpes.
- Chickenpox: Virax indicated for the treatment of chickenpox (varicella).

Contraindications

Acyclovir contraindicated for patients who develop hypersensitivity or intolerance to the components of the formulations.

Warnings

Acyclovir suspension intended for oral ingestion only.

Adverse Reactions

Skin rashes have been reported in a few patients receiving acyclovir tablets; the rashes have resolved on withdrawal of the drug.

Gastrointestinal effects, including nausea, vomiting, diarrhoea, and abdominal pains, have been reported in some patients receiving acyclovir tablets.

Other events reported rarely in patients receiving oral formulations of acyclovir include mild, transient rises in bilirubin and liver related enzymes, small increases in blood urea and creatinine, small decreases in haematological indices, headaches, mild reversible neurological reactions and fatigue.

Precautions

Dosage adjustment is recommended when administering Acyclovir to patients with renal impairment. Caution should also be exercised when administering acyclovir to patients receiving potentially nephrotoxic agents since this may increase the risk of renal dysfunction and/or the risk of reversible central nervous system symptoms such as those that have been reported in patients treated with intravenous acyclovir.

Information for Patients

Patients are instructed to consult with their physician if they experience severe or troublesome adverse reactions, they become pregnant or intend to become pregnant, they intend to breastfeed while taking orally administered Acyclovir, or they have any other questions.

Herpes Zoster: There are no data on treatment initiated more than 72 hours after onset of the zoster rash. Patients should be advised to initiate treatment as soon as possible after a diagnosis of herpes zoster.

Genital Herpes Infections: Patients should be informed that acyclovir is not a cure for genital herpes. There are no data evaluating whether Acyclovir will prevent transmission of infection to others. Because genital herpes is a sexually transmitted disease, patients should avoid contact with lesions or intercourse when lesions and/or symptoms are present to avoid infecting partners. Genital herpes can also be transmitted in the absence of symptoms through asymptomatic viral shedding. If medical management of a genital herpes recurrence is indicated, patients should be advised to initiate therapy at the first sign or symptom of an episode.

Chickenpox: Chickenpox in otherwise healthy children is usually a self-limited disease of mild to moderate severity. Adolescents and adults tend to have more severe disease. Treatment was initiated within 24 hours of the typical chickenpox rash in the controlled studies, and there is no information regarding the effects of treatment begun later in the disease course.

Pregnancy

Category C

There are no adequate and well-controlled studies in pregnant women. Acyclovir should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. The drug's potential for causing chromosome breaks at high concentration should be taken into consideration in making this determination.

Nursing Mothers

Acyclovir concentration have been documented in breast milk in two women following oral administration of Acyclovir and ranged from 0.6 to 4.1 times corresponding plasma levels. These concentrations would potentially expose the nursing infant to a dose of acyclovir up to 0.3 mg/kg/day. Caution should be exercised when Acyclovir is administered to a nursing woman.

Paediatric Use

Safety and effectiveness in pediatric patients less than two years of age have not been adequately studied.

Geriatric Use

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased renal function, and of concomitant disease or other drug therapy.

Drug Interactions

Co-administration of probenecid with intravenous acyclovir has been shown to increase acyclovir half-life and systemic exposure. Urinary excretion and renal clearance were correspondingly reduced.

Dosage and Administration

Children (Two Years of Age and Older)

20 mg/kg per dose orally four times daily (80 mg/kg/day) for five days. Children over 40 kg should receive the adult dose.

Over Dosage

Acyclovir is only partly absorbed in the gastrointestinal tract. Patients have ingested overdoses of up to 20 g acyclovir on a single occasion, usually without toxic effects. Accidental, repeated overdoses of oral acyclovir over several days have been associated with gastrointestinal effects (such as nausea and vomiting) and neurological effects (headache and confusion).

Overdosage of intravenous acyclovir has resulted in elevations of serum creatinine, blood urea nitrogen and subsequent renal failure. Neurological effects including confusion, hallucinations, agitation, seizures and coma have been described in association with intravenous overdosage.

Management

Patients should be observed closely for signs of toxicity. Haemodialysis significantly enhances the removal of acyclovir from the blood and may be considered a management option in the event of symptomatic overdose.

Presentation

Bottle of 60 ml