VIRAX

Cream

Composition

Virax Cream: Each gram contains Acyclovir 50 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 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 further 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 is 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 However, when prolonged treatment is withdrawn infections may recur.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.

The absorption of acyclovir cream through the intact skin is minimal; acyclovir is not detected in blood or urine

Indications

Virax Cream

Virax Cream 5% indicated in the management of initial herpes genitals and in limited non life-threatening mucocutaneous Herpes Simplex virus infection in immunocompromised patients. In clinical trials of initials herpes genitals, Virax Cream 5 % has shown a decrease in healing time and in some cases a decrease in duration of viral shedding and slight decrease in duration of pain. In studies in immunocompromised patients with mainly herpes labialis, there was a decrease in duration of viral shedding and a slight decrease in duration of pain.

Contraindications

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

Warnings

During treatment with this medicine, blood and urine tests should be performed. In women with genital herpes, PAP test is required. Sexual activity should be avoided if either partner has genital herpes since it is sexually transmitted.
The recommended dosage and length of treatment should not be exceeded.

In severely immunocompromised patients, the physician should be aware that prolonged or repeated courses of Acyclovir might result in selection of resistant viruses that may not fully respond to continued Acyclovir therapy.

Children treated with steroids for short and medium terms or using inhaler (it is advisable to stop corticosteroid treatment).
Caution should be exercised when administering Acyclovir to patients receiving potentially nephrotoxic agents since this may increase the risk of renal dysfunction.

There exist no data that demonstrates that the use of Acyclovir will either prevent transmission of infection to other persons or prevent infections when applied in the absence of signs & symptoms. It should not be used for the prevention of recurrent HSV infections. Although clinical significant viral resistance associated with the use of Acyclovir has not been observed, this possibility exists.

In women with genital herpes, PAP test is required at least once a year because they may be more likely to get cancer of cervix (mouth of womb).

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. If suppressive therapy is used in the prenatal period, it should not be assumed that viral shedding has ceased, or that the risk to fetus/neonate has decreased. Pregnancy should be managed according to considerations normally applicable to patients with genital herpes.

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 children have not been established.

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.

Drug Interactions

Co-administration of probenecid with intravenous acyclovir has been shown to increase the mean half-life and the area under the concentration-time curve. Urinary excretion and renal clearance were reduced.

Clinical experience has identified no interactions resulting from topical or systemic administration of other drugs concomitantly with Acyclovir.

Dosage and Administration

Virax cream

A cream containing Acyclovir 5% may be applied five or six times daily every 3 or 4 hours for periods of 5 to 10 days.

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

Virax cold sores cream

Tube of 5 grams