

CUSIVIRAL[®]

Eye ointment (Acyclovir)

COMPOSITION: Each gram of ointment contains 30 mg of acyclovir.
Excipients: s.q.

PRODUCT DESCRIPTION: Yellowish soft homogeneous ointment.

PROPERTIES: Acyclovir, active ingredient of CUSIVIRAL, is an antiviral drug with "in vitro" and "in vivo" activity against the Herpes simplex viruses types I and II and Varicella-Zoster virus. It has low toxic effect on human and mammal cells.

Once inside the herpes virus-infected cell, Acyclovir is phosphorylated to the active ingredient Acyclovir-triphosphate, the first step of this process requires the presence of a specific thymidine-kinase enzyme specific of the Herpes simplex virus. Acyclovir triphosphate acts as a specific inhibitor of DNA polymerase of herpes, preventing the subsequent synthesis of viral DNA without affecting the normal cellular processes.

Acyclovir is rapidly absorbed through the corneal epithelium and superficial ocular tissues producing concentrations in aqueous humor which are toxic for the virus. It has not been possible, by existing methods, to detect Acyclovir in blood after topical administration of CUSIVIRAL EYE OINTMENT. However, traces of the product have been found in the urine, which are devoid of therapeutic significance.

INDICATIONS: CUSIVIRAL EYE OINTMENT is indicated in the treatment of keratitis caused by Herpes simplex.

DOSAGE: The recommended dose is a small amount (about 10 mm of ointment), 5 times a day, at intervals of approximately 4 hours. Treatment should be continued for at least 3 days after healing.

CORRECT ADMINISTRATION PROCEDURE: The ointment should be administered into the lower conjunctival sac. It is recommended to keep the eye closed for 30 seconds after administration of the ointment.

CONTRAINDICATIONS: CUSIVIRAL EYE OINTMENT is contraindicated in patients with known hypersensitivity to Acyclovir.

Pregnancy: The safety of this product during pregnancy has not been demonstrated, and therefore its use is

not recommended. This product should only be used in those cases in which a previous risk/benefit evaluation justifies its use.

PRECAUTIONS: The results of a comprehensive "in vitro" and "in vivo" mutagenicity study have not demonstrated that Acyclovir presents genetic risks for humans.

INCOMPATIBILITIES: It has not been described that CUSIVIRAL EYE OINTMENT presents interaction with any other drug.

ADVERSE REACTIONS: In a small number of patients, a mild or transitory stinging may appear immediately after the administration of CUSIVIRAL EYE OINTMENT. Some cases of keratopathies have been reported, which do not require interruption of the treatment and disappear without sequelae.

Local irritation and inflammation such as blepharitis and conjunctivitis.

OVERDOSAGE: Toxic effects are unlikely to occur if the entire contents of the tube were accidentally ingested.

In the event of overdosage or accidental ingestion, consult physician or a Poison Control Center.

STORAGE: Store up to 25°C.

Discard one month after first opening the tube.

HOW SUPPLIED: 4.5 g tube →

~~KEEP ALL MEDICATION OUT OF THE REACH OF CHILDREN~~

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