VIRACYL

(Acyclovir 3%)

Gamma Irradiated

Sterile Ophthalmic Ointment

وائراسِل

اے سائیکلوور 3%

DESCRIPTION:

Viracyl (Acyclovir) Ointment is a sterile ophthalmic ointment, antiviral in nature. It is for topical ophthalmic use.

COMPOSITION:

Each gram contains:

Acyclovir.....30mg

(B.P Specs)

PHARMACOKINETICS:

Acyclovir is absorbed following application of a 3 % ointment to the eye giving a relatively high concentration of 1.7 ug per ml in the aqueous humour but negligible amount in the blood. There is a wide distribution, including into the CSF where concentration achieved is about 50% of those achieved in plasma. Protein binding is reported to range from 9 to 33% Acyclovir crosses the placenta and distributed into the breast milk in concentration approximately 3 times higher then those in maternal serum. It is excreted through the kidney by both glomerular filtration and tubular secretion. The terminal or beta phase Half life is reported to be 2-3 hours for adults without renal impairment. In Chronic liver failure this value is increased and may be upto 19.5 hours in anuric patients. Fecal excretion may account for about 2% of a dose.

Acyclovir ointment is a synthetic purine nucleoside analogue with in vitro and in vivo inhibitory activity against human herpes viruses including herpes simplex type 1 (HSV-1) and 2 (HSV-2), varicella zoster virus (VZV) Epstein Bar virus (EBV) and cytomegalovirus (CMV). In cell culture, acyclovir has the highest antiviral activity against HSV-1, followed in decreasing order of potency against (HSV-2), VZV, EBV, and CMV. The inhibitory activity of **Viracyl** for HSV-1, HSV-2, VZV, and EBV is highly selective. **Viracyl** once entered into the infected cell, then it is converted into active form acyclovir triphosphate by multi-step enzymatic phosphorylation reactions by thymidine kinase encoded by HSV,VZV and EBV. Acyclovir triphosphate interferes with herpes simplex virus DNA polymerase and inhibits viral DNA replication.

INDICATIONS:

Viracyl Sterile Ophthalmic Ointment is indicated for the treatment of herpes simplex keratitis.

CONTRAINDICATIONS:

The use of **Viracyl** Sterile Ophthalmic Ointment is contraindicated in those patients with known hypersensitivity to Acyclovir or any other component of the product.

PRECAUTIONS:

1. General: Patient may experience mild transient stinging immediately following administration.

2. Mutagenicity: The in-vivo and in-vitro Mutagenicity tests conducted with acyclovir have not revealed any mutagenic effects in humans.

3. Carcinogenicity: In long term animal studies with acyclovir conducted on the rats and the mice have not shown any carcinogenic effects.

4. Pregnancy: Acyclovir should not be used during pregnancy unless the potential benefit justifies the potential risks to the fetus.

5. Nursing Mothers: Limited human data have shown that acyclovir is excreted in milk.

6. Pediatric use: Safety and efficacy in children less than 2 years of age have not been adequately studied.

DRUG INTERACTIONS:

Co-administration of probenecid with intravenous acyclovir have been shown to increase the mean half-life and the area under curve of acyclovir. Other drugs affecting renal physiology may affect renal clearance of acyclovir.

DOSAGE AND ADMINISTRATION:

Apply 10 mm ribbon of the ointment into-the lower conjunctival sac 5 times a day at approximate ly 4 hours intervals. Treatment should be continued for at least 3 days after healing.

ADVERSE REACTIONS:

Patient may experience mild transient stinging immediately following administration. The adverse reaction following topical ophthalmic administration of acyclovir ophthalmic ointment have superficial punctate keratopathy however this do not require termination of treatment and heal-up without apparent sequalae. Other reactions include inflammation, blepharitis and conjunctivitis.

WARNINGS:

For topical ophthalmic use only. To be sold on the prescription of a registered medical practitioner only. Use within four weeks after the first opening. Do not touch the tip of the tube.

STORAGE CONDITIONS:

Store between 15-30° C. Protect from heat, sunlight and freezing. Keep out of the reach of the children.

PRESENTATION:

Viracyl Sterile Ophthalmic Ointment is supplied as a pack of 4 grams in tubes (Gamma Irradiated)

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

ہدایات: دوا کو دھوپ، گرمی اور منجمد ہونے سے بچائیں۔

دوا کو بچوں کی پہنچ سے دور رکھیں۔

15سے30ڈگری سینٹی گریڈ کے درمیان رکھیں۔

احتیاط: پہلی مرتبہ ٹیوب کھولنے کے ۴ ہفتے تک دوا قابل استعمال رہتی ہے۔

انتباہ:

صرف رجسٹرڈ میڈیکل پریکٹیشنز کے نسخے پر فروخت کے لیے۔

Manufactured by:
Vega Pharmaceuticals (Pvt.) Ltd.
30km, Multan Road, Lahore-Pakistan.