

Xoviral

Ganciclovir USP 0.15 %
Sterile Ophthalmic Gel

Composition:

Xoviral Sterile Ophthalmic Gel: Each gram gel contains Ganciclovir USP 1.5 mg.

Pharmacology:

Ganciclovir, a guanosine derivative, is transformed by viral and cellular thymidine kinases (TK) to Ganciclovir triphosphate, which works as an antiviral agent by inhibiting the synthesis of viral DNA in 2 ways: competitive inhibition of viral DNA-polymerase and direct incorporation into viral primer strand DNA, resulting in DNA chain termination and prevention of replication.

Indications:

Xoviral Sterile Ophthalmic Gel is indicated for the treatment of acute herpetic keratitis (dendritic ulcers).

Dosage & administration:

Instill 1 drop in the affected eye 5 times per day (approximately every 3 hours while awake) until the corneal ulcer heals and then 1 drop 3 times per day for 7 days.

Contraindications:

None.

Side effects:

Most common adverse reactions reported in patients are blurred vision, eye irritation, punctate keratitis and conjunctival hyperemia.

Precautions:

- Ganciclovir is indicated for topical ophthalmic use only.
- Patients should not wear contact lenses if they have signs or symptoms of herpetic keratitis or during the course of therapy with Ganciclovir.
- Patients should be advised not to allow the dropper tip to touch any surface, as this may contaminate the gel.

Use in special group:

Use in pregnancy: Pregnancy category C. There are no adequate and well-controlled studies in pregnant women. Ganciclovir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in lactation: It is not known whether topical ophthalmic Ganciclovir administration could result in sufficient systemic absorption to produce detectable quantities in breast milk. Caution should be exercised when Ganciclovir is administered to nursing mothers.

Use in children: Safety and efficacy in pediatric patients below the age of 2 years have not been established.

Use in elderly patients: No overall differences in safety or effectiveness have been observed between elderly and younger patients.

Storage:

- Store below 30°C, in a dry place, protect from light.
- Do not use longer than 30 days after first opening.
- Keep out of the reach of children.

Packing:

Xoviral Sterile Ophthalmic Gel: Each tube contains 5 g sterile ophthalmic gel.

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Manufactured by:
ARISTOPHARMA LTD.
SHAMPUR-DHAKA-BANGLADESH