

SUPPORT DOCUMENT I: Topical Antiviral Agents

All of the information below was obtained from the prescribing information (“package insert”) supplied by the manufacturers.

Two topical antivirals available in the United States (both FDA approved for HSV epithelial keratitis)

Zirgan® (Ganciclovir Ophthalmic Gel 0.15%)

FDA Approval

Indications: Acute HSV keratitis (dendritic ulcers).

Pediatrics: Children age 2 and above.

Pregnancy: Category C.

Nursing Mothers: Caution should be exercised.

Warnings: Avoid Contact Lenses.

Dosage: 1 drop 5 times daily (Q 3 hours while awake) until healed then 1 drop TID for 1 week.

Adverse Reactions: Blurred vision (60%), eye irritation (20%), punctuate keratitis (5%), and conjunctival hyperemia (5%).

Cost per treatment course according to the Veterans Affairs Administration: open market price as of 5/3/10: \$127.48.

Viroptic® (Trifluridine Ophthalmic Solution 1%)

FDA Approval

Indications: Primary keratoconjunctivitis and recurrent epithelial keratitis due to HSV, types I & II.

Pediatrics: Children age 6 and above.

Pregnancy: Category C.

Nursing Mothers: Should not be prescribed to nursing mothers unless the potential benefits outweigh potential risks.

Warnings: Do not exceed maximum dose due to toxicity.

Dosage: 1 drop Q 2 hours while awake (do not exceed 9 drops per day) until healed then 1 drop 5 times a day for 1 week.

Max Dose: Daily (9 drops), total number of days (21 days).

Adverse Reactions: Mild burning or stinging upon instillation (4.6%) and palpebral edema (2.8%). Other symptoms less than 2.8%: punctuate keratitis, epithelial keratopathy, hypersensitivity reaction, stromal edema, irritation, keratitis sicca, hyperemia, and increased intraocular pressure.

(Trifluridine Ophthalmic Solution 1%, generic)

FDA Approval

Indications: Primary keratoconjunctivitis and recurrent epithelial keratitis due to HSV, types I & II.

Pediatrics: Children age 6 and above.

Pregnancy: Category C.

Nursing Mothers: Should not be prescribed to nursing mothers unless the potential benefits outweigh potential risks.

Warnings: Do not exceed maximum dose due to toxicity.

Dosage: 1 drop Q 2 hours while awake (do not exceed 9 drops per day) until healed then 1 drop 5 times a day for 1 week.

Max Dose: Daily (9 drops), total number of days (21 days).

Adverse Reactions: Mild burning or stinging upon instillation (4.6%) and palpebral edema (2.8%). Other symptoms less than 2.8%: punctuate keratitis, epithelial keratopathy, hypersensitivity reaction, stromal edema, irritation, keratitis sicca, hyperemia, and increased intraocular pressure.

Cost per treatment course according to the Veterans Affairs Administration: open market price as of 5/3/10: \$39.20.