

# Fludin

Trifluridine USP 1%  
Sterile Eye Drops

**Composition:**

**Fludin Sterile Eye Drops:** Each ml contains Trifluridine USP 10 mg.

**Pharmacology:**

Trifluridine is a fluorinated pyrimidine nucleoside analog which interferes with DNA synthesis of herpes simplex virus, type 1 and 2 and vaccinia virus. It stops replication of herpes viral DNA in 3 ways: i) competitive inhibition of viral DNA polymerase, ii) incorporation into and termination of the growing viral DNA chain and iii) inactivation of the viral DNA polymerase.

**Indications:**

Fludin Sterile Eye Drops is indicated for the treatment of primary keratoconjunctivitis and recurrent epithelial keratitis due to herpes simplex virus, type 1 and 2.

**Dosage & administration:**

Children above 6 years of age & adults: Instill 1 drop every 2 hrs. while awake; maximum 9 drops/day until the corneal ulcer has completely re-epithelialized. After re-epithelialization: Instill 1 drop every 4 hrs. or at least 5 drops/day for 7 days is recommended.

If there are no signs of improvement after 7 days of therapy or complete re-epithelialization has not occurred after 14 days of therapy, other forms of therapy should be considered. Continuous administration of Fludin eye drops for periods exceeding 21 days should be avoided because of potential ocular toxicity.

**Contraindications:**

Contraindicated in patients who develop hypersensitivity reactions or chemical intolerance to Trifluridine.

**Side effects:**

Reported side effects are mild, transient burning or stinging sensation upon instillation. Other side effects are superficial punctate keratopathy, epithelial keratopathy, hypersensitivity reaction, stromal edema, irritation, keratitis sicca, hyperemia and increased intraocular pressure.

**Precautions:**

Trifluridine should be prescribed only for patients who have a clinical diagnosis of herpetic keratitis.

**Use in special group:**

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

**Use in lactation:** It is unlikely that Trifluridine is excreted in human milk after instillation of eye drops because of the relatively small dosage. The drug should not be prescribed for nursing mothers unless the potential benefits outweigh the potential risks.

**Use in children:** Safety and effectiveness in pediatric patients below 6 years of age have not been established.

**Use in elderly patients:** No overall clinical differences in safety or effectiveness have been observed between elderly and other adult patients.

**Storage:**

- Store between 2<sup>o</sup> to 8<sup>o</sup> C.
- Do not use longer than 30 days after first opening.
- Keep out of the reach of children.

**Packing:**

**Fludin Sterile Eye Drops:** Each plastic dropper bottle contains 5 ml/10 ml sterile eye drops.



Manufactured by:  
**ARISTOPHARMA LTD.**  
SHAMPUR-DHAKA-BANGLADESH

PIF-013/01