

## Avaclyr™ (acyclovir) – New orphan formulation approval

- On April 1, 2019, [Fera Pharmaceuticals announced](#) the FDA approval of [Avaclyr \(acyclovir\)](#) 3% ophthalmic ointment, for the treatment of acute herpetic keratitis (dendritic ulcers) in patients with herpes simplex (HSV-1 and HSV-2) virus.
- Acyclovir is also available generically as an [injectable solution](#), oral [capsule](#), oral [tablet](#), oral [suspension](#), and topical [ointment](#). It is also available as a brand buccal tablet ([Sitavig](#)®), topical cream ([Zovirax](#)®), and in combination with hydrocortisone ([Xerese](#)®),
  - The injection is indicated for the treatment of herpes simplex and varicella-zoster infections in immunocompromised patients; initial episodes of herpes genitalis; herpes simplex encephalitis; and neonatal herpes simplex virus infection.
  - The oral capsule, tablet and suspension are indicated for herpes zoster infections, initial and recurrent genital herpes infections, and chickenpox (varicella).
  - The ointment is indicated for the management of initial genital herpes and in limited non-life-threatening mucocutaneous herpes simplex virus infections in immunocompromised patients.
  - Sitavig and Zovirax cream are indicated for the treatment of recurrent herpes labialis (cold sores) in immunocompetent patients.
  - Xerese is indicated for the early treatment of recurrent herpes labialis (cold sores) to reduce the likelihood of ulcerative cold sores and to shorten the lesion healing time.
- The approval of Avaclyr was based on studies that enrolled 238 subjects with dendritic herpetic keratitis.
  - Avaclyr was either superior or as effective as idoxuridine ophthalmic ointment (not approved in the U.S.) in patients with dendritic ulcers.
  - Clinical resolution (healed ulcers) at day 7 averaged 83% for Avaclyr vs. 50% for idoxuridine.
- The most common adverse reactions (2 – 10%) with Avaclyr use were eye pain (stinging), punctate keratitis and follicular conjunctivitis.
- The recommended dosing regimen of Avaclyr is to apply a 1 cm ribbon of ointment in the lower cul-de-sac of the affected eye 5 times per day (approximately every 3 hours while awake) until the corneal ulcer heals and then a 1 cm ribbon 3 times per day for 7 days.
- Fera Pharmaceuticals' launch plans for Avaclyr are pending.