



Dextenza[®] (dexamethasone ophthalmic insert) – New drug approval

- On December 3, 2018, [Ocular Therapeutix announced](#) the FDA approval of [Dextenza \(dexamethasone ophthalmic insert\)](#), for the treatment of ocular pain following ophthalmic surgery.
- Dextenza is the first preservative-free corticosteroid intracanalicular insert. Dextenza is placed in the punctum, a natural opening in the inner portion of the lower eyelid, and into the canaliculus.
- The efficacy of Dextenza was based on two vehicle-controlled studies enrolling 488 patients. Dextenza or its vehicle was placed immediately after cataract surgery.
 - In both studies, Dextenza had a higher incidence of patients who were pain free at post-operative days 2, 4 and 8.
- Dextenza is contraindicated in patients with active corneal, conjunctival or canalicular infections, including epithelial herpes simplex keratitis (dendritic keratitis), vaccinia, varicella; mycobacterial infections; fungal diseases of the eye, and dacryocystitis.
- Other warnings and precautions of Dextenza include intraocular pressure increase, bacterial infection, viral infections, fungal infections, and delayed healing.
- The most common adverse reactions (5 – 9%) with Dextenza use were anterior chamber inflammation and elevations in intraocular pressure.
- The recommended dose of Dextenza is one ophthalmic insert that is inserted in the lower lacrimal punctum into the canaliculus by a physician. A single Dextenza releases a 0.4 mg dose of dexamethasone for up to 30 days following insertion.
 - Dextenza is resorbable and does not require removal.
 - Saline irrigation or manual expression can be performed to remove the insert if necessary.
- Ocular Therapeutix's launch plans for Dextenza are pending. Dextenza will be available as an ophthalmic intracanalicular insert containing a 0.4 mg dose of dexamethasone.



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