

What is Akten®?

- **Akten®**, (lidocaine hydrochloride) Ophthalmic Gel 3.5%, is a prescription topical ocular anesthetic. It is the first FDA-Approved ophthalmic gel anesthetic in an optimal 3.5% dose and is preservative free.

What are the features and benefits of Akten®?

- Onset of action between 20 to 60 seconds and persists for 5 to 30 minutes or more
- Viscous gel formulation for extended localized contact
- Only FDA-approved lidocaine available for ocular procedures
- Physiological pH: 5.5 to 7.5
- Store at room temperature: 15° to 25°C (59° to 77°F)
- Preservative free

What is Akten® indicated for?

- **Akten®** is a local anesthetic indicated for ocular surface anesthesia during ophthalmologic procedures.

What procedures will use Akten®?

- Any procedure where a topical anesthetic would be used including: prior to cataract surgery, intravitreal injections, refractive surgery including LASIK, supplemental topical anesthetic after peribulbar or retrobulbar block, contact lens exam of retina, ALT/SLT lasers, retinal lasers, retinal cryoretinopexy, pneumatic retinopexy, scleral depression examinations, conjunctival or corneal foreign body removal, gonioscopy, suture placement, removal of corneal sutures, removal of conjunctival sutures, removal of lid sutures, anterior chamber paracentesis, placement of electroretinographic lenses, lens placement for YAG laser, vitreous biopsy, conjunctival biopsies, minor lid procedures, pterygium surgery, strabismus adjustment surgery, conductive keratoplasty, pars plana vitrectomy, and trabeculectomy.

How is Akten® administered?

- The recommended dose of **Akten®** is 2 drops applied to the ocular surface in the area of the planned procedure.
- **Akten®** may be reapplied to maintain anesthetic effect.

What are the ingredients of Akten®?

- **Actives:** 35 mg of Lidocaine Hydrochloride;
- **Preservative:** None;
- **Inactives:** Hypromellose, Sodium Chloride, and Purified Water as inactive ingredients. The pH may be adjusted to 5.5 to 7.5 with Hydrochloric Acid and/or Sodium Hydroxide.

How is Akten® Packaged?

- **Akten®** is supplied in a single use 5mL/10cc in a clear plastic ophthalmic dropper bottle
- NDC# 17478-792-10
- Sold in an eaches (1) and shrink wrapped in 12s

How is Akten[®] used in specific populations?

- **Pregnancy** - Reproduction studies for lidocaine have been performed in both rats and rabbits. There was no evidence of harm to the fetus at subcutaneous doses up to 50 mg/kg lidocaine (more than 800 fold greater than the human dose on a body weight basis) in the rat model. There are however, no adequate and well controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used in pregnancy only if clearly needed.
- **Nursing Mothers** - Lidocaine is secreted in human milk. The clinical significance of this observation is unknown. Although no systemic exposure is expected with administration of **Akten[®]**, caution should be exercised when **Akten[®]** is administered to a nursing woman.
- **Pediatric Use** - Safety and efficacy in pediatric patients has been extrapolated from studies in older subjects and studies in pediatric patients using different formulations of lidocaine.
- **Geriatric Use** - No overall clinical differences in safety or effectiveness were observed between the elderly and other adult patients.

What important safety information should I know about Akten[®]?

- **Akten[®]** has no known contraindications. Most common adverse reactions are conjunctival hyperemia, corneal epithelial changes, headache, and burning upon instillation.
- To report SUSPECTED ADVERSE REACTIONS, contact Akorn at (1-800-932-5676 and www.Akorn.com) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

What is the shelf life of Akten[®]?

- **Akten[®]** has a 24 month shelf life

How should Akten[®] be stored?

- Store between 15° to 25°C (59° to 77°F)
- Keep container closed and protected from light in the original carton until use
- Discard after use