3.5% Viscous Topical Ocular Anesthetic Gel Preservative Free

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

**Akten® (lidocaine hydrochloride ophthalmic gel) 3.5%**

<table>
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<tr>
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<th>DESCRIPTION</th>
<th>SIZE</th>
<th>UNIT OF SALE</th>
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<td>17478-792-01</td>
<td>3.5% Sterile Ophthalmic Gel in a Unit-dose Tube</td>
<td>1 mL</td>
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<tr>
<td>17478-792-25</td>
<td>3.5% Sterile Ophthalmic Gel in a Unit-dose Tube</td>
<td>1 mL</td>
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**Each mL Contains**

**ACTIVE:** 35 mg of Lidocaine Hydrochloride;  
**PRESERVATIVE:** None;  
**INACTIVES:** Hypromellose, Sodium Chloride, and Water for Injection. The pH may be adjusted to 5.5 to 7.5 with Hydrochloric Acid and/or Sodium Hydroxide.  
**STORAGE:** Store at 15° to 25°C (59° to 77°F). Keep container closed and protected from light in the original carton until use. Discard after use.

<table>
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<th>NDC</th>
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<th>AMERISOURCEBERGEN</th>
<th>MCKESSON</th>
<th>MORRIS DICKSON</th>
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Akten® is indicated for ocular surface anesthesia during ophthalmologic procedures.

**IMPORTANT SAFETY INFORMATION**

Akten® has no known contraindications. Most common adverse reactions are conjunctival hyperemia, corneal epithelial changes, headache, and burning upon instillation.

**To order products call 800-932-5676 or fax 800-943-3694 • akten.com**

**NOT FOR PRESCRIBING PURPOSES. PLEASE REFER TO PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION.**
The recommended dose of AKTEN® is 2 drops applied to the ocular surface in the area of the planned procedure. Additional anesthesia may be reapplied as needed. (2)

### ADVERSE REACTIONS

Most common adverse reactions are conjunctival hyperemia, corneal epithelial changes, headache, and burning upon instillation.

### USE IN SPECIFIC POPULATIONS

#### 8.1 Pregnancy

Pregnancy Category B.

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.

#### 8.3 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.

#### 8.4 Pediatric Use

Safety and efficacy in pediatric patients have been extrapolated from studies in older subjects and studies in pediatric patients using different formulations of lidocaine.

#### 10 OVERDOSAGE

Prolonged use of a topical ocular anesthetic may produce permanent corneal opacification and ulceration with accompanying visual loss. (5)

### CONTRAINDICATIONS

None. (4)

### Warnings and Precautions

- Not for injection.
- Corneal Opacification. Prolonged use of a topical ocular anesthetic may produce permanent corneal opacification and ulceration with accompanying visual loss.