

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**21-996**

**LABELING**

<b>Directions</b> Instill 1 drop in the affected eye(s) twice daily.	See carton for full Drug Facts information.	KETOTIFEN FUMARATE OPHTHALMIC SOLUTION ANTIHISTAMINE EYE DROPS	<i>Alaway</i>
<b>ALIMERA</b> SCITTKCEY	© 2005 Alimera Sciences, Inc. Alpharetta, GA 30005	STERILE 0.34 FL OZ (10 ML)	



NETOPHEN FUMARATE Ophthalmic Solution

NDC 890411-048-10



NETOPHEN FUMARATE  
OPHTHALMIC SOLUTION

ITCH RELIEF WITHIN MINUTES  
UP TO 12-HOUR RELIEF

STERILE Ophthalmic Solution (10mL)

**Alaway**

ITCH RELIEF WITHIN MINUTES  
UP TO 12-HOUR RELIEF

**ALIMERA**  
SCIENCE

Distributed by Alimera Sciences, Inc.  
Elyria, OH 44025  
U.S. Patent Pending  
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**Drug Facts**

<b>Active ingredient</b> Ketotifen 0.025% (equivalent to ketotifen fumarate 0.035%)	<b>Purpose</b> Antihistamine
<b>Uses</b> For the temporary relief of itchy eyes due to ragweed, pollen, grass, animal hair and dander.	
<b>Warnings</b>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>■ if you are sensitive to any ingredient in this product</li> <li>■ if the solution changes color or becomes cloudy</li> <li>■ to treat contact lens related irritation</li> </ul>	
<b>When using this product</b>	
<ul style="list-style-type: none"> <li>■ remove contact lenses before use</li> <li>■ wait at least 10 minutes before re-inserting contact lenses after use</li> <li>■ do not touch the tip of the container to any surface to avoid contamination</li> <li>■ replace cap after each use</li> </ul>	
<b>Stop use and ask a doctor if you experience any of the following:</b>	
<ul style="list-style-type: none"> <li>■ eye pain</li> <li>■ changes in vision</li> <li>■ redness of the eyes</li> <li>■ itching that worsens or lasts for more than 72 hours</li> </ul>	
<b>Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.</b>	

**Drug Facts**  
(continued)

**Directions**  
Adults and children 3 years and older: put 1 drop in the affected eye(s) twice daily, every 8-12 hours, no more than twice per day. Children under 3 years of age: consult a doctor.

**Other information**  
Store at 4 – 25°C (39 – 77°F)

**Inactive ingredients**  
Benzalkonium chloride, 0.01%, glycerin, sodium hydroxide and/or hydrochloric acid and water for injection.

**Questions?**  
Call 1-800-990-5770  
Monday – Friday  
9AM – 5PM EST



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