

NDA 21-066/S-001  
Page 3

Do not use if seal on bottle is missing or broken.

0078-9475-61

NOVARTIS

# ZADITOR<sup>®</sup>

ketotifen fumarate ophthalmic solution  
ANTHISTAMINE EYE DROPS

up to  
**12**  
HOURS

**EYE ITCH RELIEF**

- Works in Minutes
- Original Prescription Strength

**SAMPLE NOT FOR SALE**

for ages 3 years and older

1 mL (0.03 FL OZ) Sterile

Made in Canada for:  
Novartis Pharmaceuticals Corp.  
East Hanover, NJ 07936  
© Novartis

www.ZADITOR.com

K758D6

**Drug Facts** (continued)

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

**Other information** ■ Only for use in the eye. ■ Store between 4°-25°C (39°-77°F).

**Inactive ingredients** benzalkonium chloride 0.01%, glycerol, sodium hydroxide and/or hydrochloric acid, and purified water

**Questions?** call toll-free 1-866-395-6336, weekdays, 8:30 AM - 5:00 PM EST

**Drug Facts**

**Active ingredient**  
Ketotifen (0.025%) (equiv. to ketotifen fumarate 0.035%).....Anthistamine

**Use** ■ Temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dander.

**Warnings**  
Do not use ■ if solution changes color or becomes cloudy ■ if you are sensitive to any ingredient in this product ■ to treat contact lens related irritation

**Drug Facts** (continued)

**When using this product** ■ do not touch tip of container to any surface to avoid contamination ■ remove contact lenses before use ■ wait at least 10 minutes before reinserting contact lenses after use ■ replace cap after each use

**Stop use and ask a doctor** if you experience any of the following: ■ eye pain ■ changes in vision ■ redness of the eye ■ itching worsens or lasts for more than 72 hours

**Keep out of reach of children.** If swallowed, get medical help or contact a Poison Control Center right away.

**Directions** ■ Children under 3 years of age: Consult a doctor.

K758D6





**Drug Facts**  
(continued)

**Inactive ingredients**  
benzalkonium chloride  
0.01%, glycerol, sodium  
hydroxide and/or  
hydrochloric acid, and  
purified water

**Questions?**  
call toll-free  
1-866-393-6336, weekdays,  
8:30 AM - 5:00 PM EST

Do not use if seal on bottle  
is missing or broken.

NDA 21-066/S-011  
Page 4

**NOVARTIS**  
Made in Canada for:  
Novartis Pharmaceuticals Corp.  
East Hanover, NJ 07936  
© Novartis  
[www.ZADITOR.com](http://www.ZADITOR.com)

**NOW OTC!**

NDC 0078-0476-61

**NOVARTIS**

**ZADITOR**<sup>®</sup>

ketotifen fumarate ophthalmic solution  
ANTIHISTAMINE EYE DROPS

up to  
**12**  
HOURS  
**EYE ITCH RELIEF**

• **Works in Minutes**  
• **Original Prescription Strength**  
for ages 3 years and older  
30 day supply  
**5 mL (0.17 FL OZ)**      **Sterile**

**ZADITOR**<sup>®</sup>

Original Prescription  
Strength  
•  
**Up to 12 Hour  
Itch Relief**

**30 DAY SUPPLY**

Works in Minutes  
•  
For Ages  
**3 Years and Older**



K759D6

**Drug Facts**

Active ingredient	Purpose
Ketotifen (0.025%)	Antihistamine
(equivalent to ketotifen fumarate 0.035%)	

**Use**  
Temporarily relieves itchy eyes due to pollen,  
ragweed, grass, animal hair and dander.

**Warnings**  
**Do not use**  
■ if solution changes color or becomes cloudy  
■ if you are sensitive to any ingredient in this product  
■ to treat contact lens related irritation

**When using this product**  
■ do not touch tip of container to any surface to  
avoid contamination  
■ remove contact lenses before use  
■ wait at least 10 minutes before reinserting contact  
lenses after use      ■ replace cap after each use

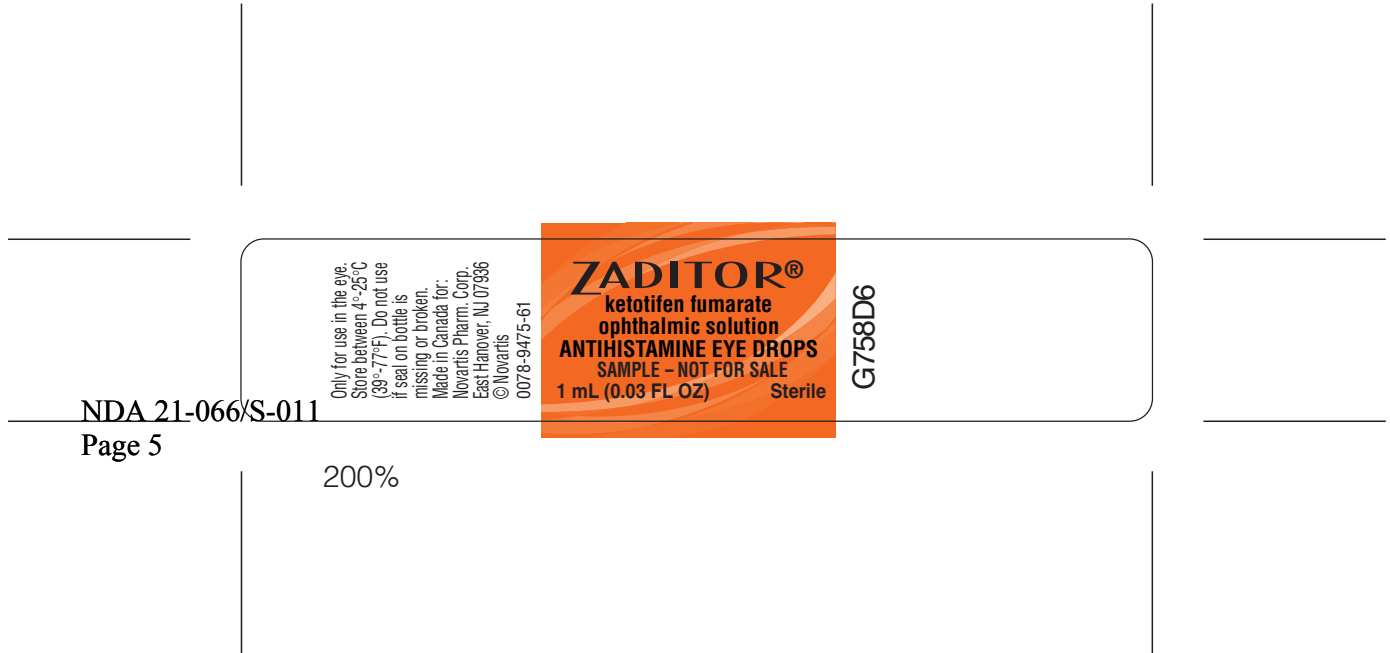
**Stop use and ask a doctor** if you experience  
any of the following:      ■ eye pain  
■ changes in vision      ■ redness of the eye  
■ itching worsens or lasts for more than 72 hours

**Keep out of reach of children.** If swallowed, get medical  
help or contact a Poison Control Center right away.

**Directions**  
■ **Adults and children 3 years of age 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**  
■ Only for use in the eye.  
■ Store between 4°-25°C (39°-77°F).

K759D6



PMS 1595C

Only for use in the eye.  
Store between 4°-25°C (39°-77°F).  
Do not use if seal on bottle  
is missing or broken.  
Made in Canada for:  
Novartis Pharmaceuticals Corp.  
East Hanover, NJ 07936  
© Novartis

NDC 0078-0476-61  
**ZADITOR**<sup>®</sup>  
ketotifen fumarate  
ophthalmic solution  
ANTI-HISTAMINE EYE DROPS  
**5 mL (0.17 FL OZ) Sterile**

G759D6

NDA 21-066/S-011  
Page 6

200%

1/4" no print / no varnish

Only for use in the eye.  
Store between 4°-25°C (39°-77°F).  
Do not use if seal on bottle  
is missing or broken.  
Made in Canada for:  
Novartis Pharmaceuticals Corp.  
East Hanover, NJ 07936  
© Novartis

NDC 0078-0476-61  
**ZADITOR**<sup>®</sup>  
ketotifen fumarate  
ophthalmic solution  
ANTI-HISTAMINE EYE DROPS  
**5 mL (0.17 FL OZ) Sterile**

G759D6

3/8" no print / no varnish  
# and expiration date  
imprinted here