PATADAY ONCE DAILY RELIEF- olopatadine hydrochloride solution Alcon Laboratories, Inc.

Drug Facts

Active Ingredients	Purpose
Olopatadine (0.7%) (equivalent to olopatadine hydrochloride 0.776%)	Antihistamine

Use temporarily relieves itchy eyes due to pollen, ragweed, grass, animal hair and dander

Warnings For external use only

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
- do not wear a contact lens if your eye is red

Stop use and ask a doctor if you experience:

- eye pain
- changes in vision
- increased 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 2 years of age and older:
 - put 1 drop in the affected eye(s) once daily
 - do not use more than 1 drop in each eye per day
 - if using other ophthalmic products while using this product, wait at least 5 minutes between each product
 - replace cap after each use

• children under 2 years of age: consult a doctor

Other information

- only for use in the eye
- store between 2°-25°C (36°-77°F)

Inactive ingredients

benzalkonium chloride 0.015%, boric acid, hydrochloric acid/sodium hydroxide (to adjust pH), hydroxypropylgamma- cyclodextrin, hypromellose, mannitol, polyethylene glycol 400, povidone, and purified water

Questions?

In the U.S., call 1-800-757-9195 or email alcon.medinfo@alcon.com

PRINCIPAL DISPLAY PANEL EXTRA STRENGTH

Pataday®

ONCE DAILY RELIEF

Olopatadine hydrochloride ophthalmic solution 0.7% Antihistamine

Eye Allergy Itch Relief

FULL 24 HOUR

Works in Minutes Relief from Allergens:

- Pet Dander
- Pollen
- Grass
- Ragweed

Alcon

STERILE 2.5 mL (0.085 FL OZ)

EXTRA STRENGTH

Pataday[®]

ONCE DAILY RELIEF

TAMPER EVIDENT: For your protection, this bottle has a seal imprinted with Alcon around the neck. Do not use if seal is damaged or missing at time of purchase.

30 DAY SUPPLY

Eye Allergy Itch Relief Works in Minutes For Ages 2 and Older

Fill Line____

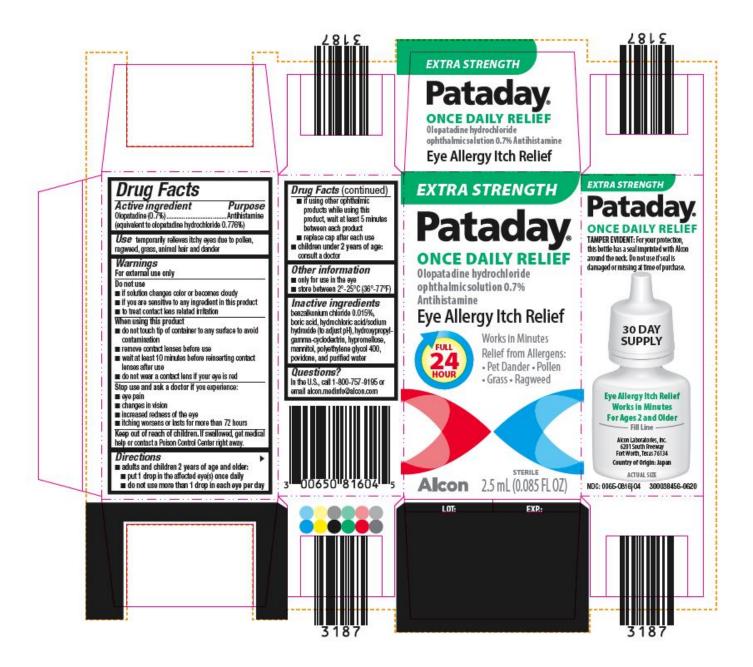
Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, Texas 76134 Country of Origin: Japan

ACTUAL SIZE

NDC: 0065-0816-04 300038456-0620

LOT: EXP.:

3187



EXTRA STRENGTH

Pataday®
ONCE DAILY RELIEF
Olopatadine hydrochloride
ophthalmic solution 0.7% Antihistamine

2.5 mL (0.085 FL OZ) STERILE

Only for use in the eye. Store between 2°- 25° C (36°- 77° F)

TAMPER EVIDENT: For your protection, this bottle has a seal imprinted with Alcon around the neck. Do not use if seal is damaged or missing at time of purchase.

Alcon Laboratories, Inc. 6201 South Freeway Fort Worth, TX 76134

LOT: EXP.:

300038442-0620



PATADAY ONCE DAILY RELIEF

olopatadine hydrochloride solution

Product Information

Product Type HUMAN OTC DRUG Item Code (Source) NDC:0065-0816

Route of Administration OPHTHALMIC

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
Olopatadine Hydrochloride (UNII: 2XG66W44KF) (Olopatadine - UNII:D27V6190PM)	Olopatadine	7 mg in 1 mL	

Inactive Ingredients		
Ingredient Name	Strength	
Benzalkonium Chloride (UNII: F5UM2KM3W7)		
Boric Acid (UNII: R57ZHV85D4)		
Hydrochloric Acid (UNII: QTT17582CB)		
Sodium Hydroxide (UNII: 55X04QC32I)		
Hydroxypropyl .GammaCyclodextrin (UNII: P6BYU725IU)		
Hypromellose, Unspecified (UNII: 3NXW29V3WO)		
Mannitol (UNII: 3OWL53L36A)		
Polyethylene Glycol 400 (UNII: B697894SGQ)		
Povidone, Unspecified (UNII: FZ989GH94E)		
Water (UNII: 059QF0KO0R)		

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0065- 0816-04	1 in 1 CARTON	09/01/2020	
1		2.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:0065- 0816-01	2 in 1 CARTON	01/04/2021	
2		2.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:0065- 0816-02	1 in 1 CARTON	01/04/2021	
3		0.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:0065- 0816-12	3 in 1 CARTON	01/24/2022	
4		2.5 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA206276	09/01/2020	

Labeler - Alcon Laboratories, Inc. (008018525)

Establishment				
Name	Address	ID/FEI	Business Operations	
Alcon Research LLC		007672236	manufacture(0065-0816)	

Revised: 6/2022 Alcon Laboratories, Inc.