

OLOPATADINE HYDROCHLORIDE- olopatadine hydrochloride solution/ drops
Apotex Corp.

Drug Facts

Active ingredient

Olopatadine (0.2%) (equivalent to olopatadine hydrochloride 0.222%)

Purpose

Antihistamine

Uses

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 and older:**
 - put 1 drop in the affected eye(s) once daily, no more than once 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°C to 25°C (36°F to 77°F)

Inactive ingredients

benzalkonium chloride 0.01%, dibasic sodium phosphate, edetate disodium dihydrate, hydrochloric acid and/or sodium hydroxide (to adjust pH), povidone, sodium chloride and water for injection

Questions?

1-800-706-5575

Principal Display Panel

ONCE DAILY RELIEF

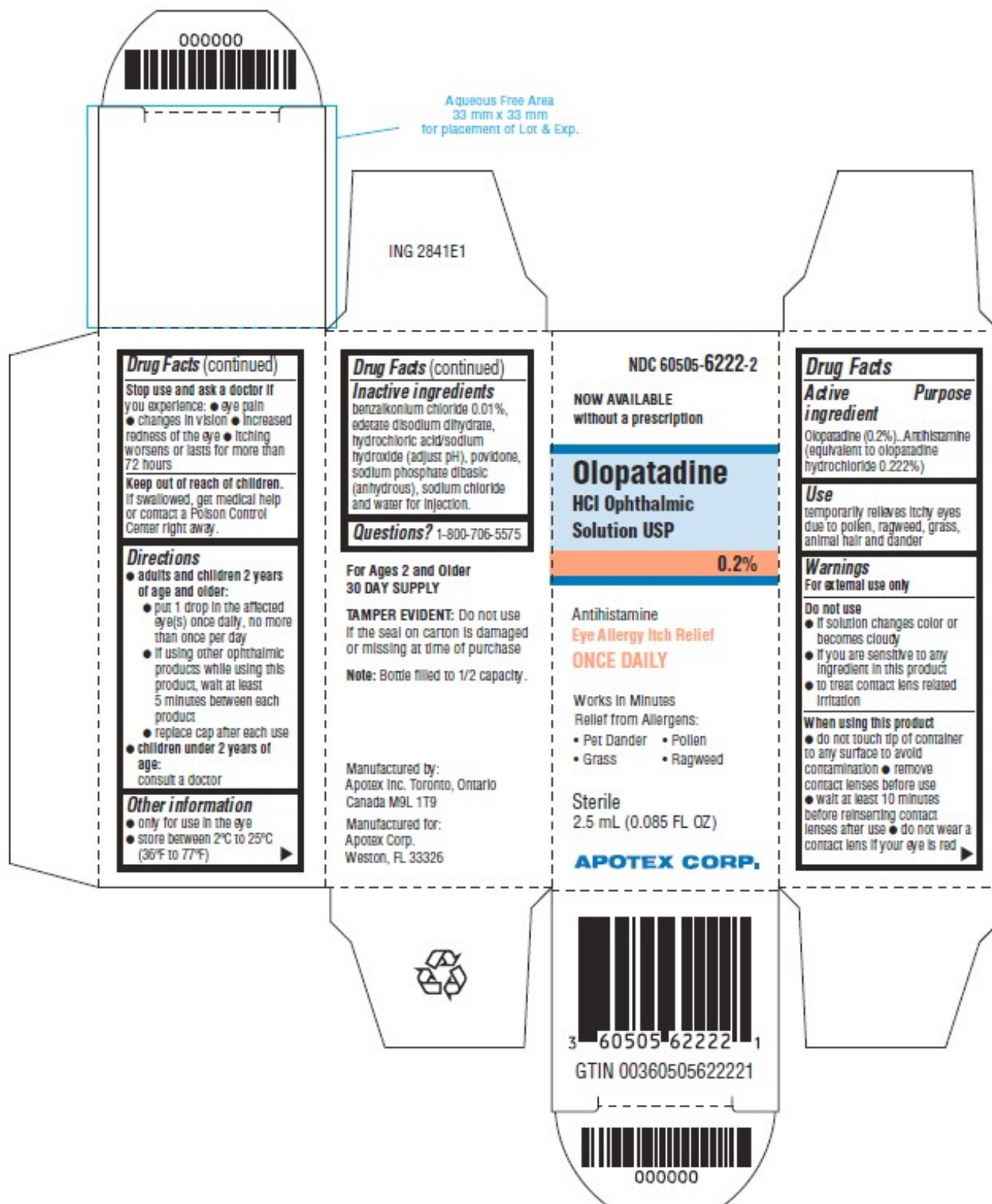
Olopatadine HCl Ophthalmic Solution, USP 0.2%

Antihistamine

Eye Allergy Itch Relief

NDC 60505-6222-2

The image shows the principal display panel for Olopatadine HCl Ophthalmic Solution USP 0.2%. The panel is rectangular with a white background. On the left side, there is a vertical black bar with white text that reads "FOR PHOTON ONLY" and a barcode. To the right of the barcode, the text "2.5 mL (0.085 FL OZ)" and "NDC 60505-6222-1" is printed. Below this, the product name "Olopatadine HCl" is printed in large, bold, black letters, followed by "Ophthalmic Solution USP" in smaller, bold, black letters. A red horizontal bar with the text "0.2%" is positioned below the product name. To the right of the red bar, the word "Sterile" is printed in bold, black letters. Below the product name and "Sterile", the text "ONCE DAILY Antihistamine EYE ALLERGY ITCH RELIEF" is printed in bold, black letters. At the bottom of the panel, the text "APOTEX CORP." is printed in bold, black letters. On the right side of the panel, there is a block of text that reads: "Only for use in the eye. Store between 2°C to 25°C (36°F to 77°F) TAMPER EVIDENT: Do not use if the seal on carton is damaged or missing at time of purchase Mfg. by: Apotex Inc. Toronto, Ontario Canada M9L 1T9 000000".



OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution/ drops

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:60505-6222
Route of Administration	OPHTHALMIC		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
OLOPATADINE HYDROCHLORIDE (UNII: 2XG66W44KF) (Olopatadine - UNII:D27V6190PM)	Olopatadine	2 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
SODIUM PHOSPHATE, DIBASIC, ANHYDROUS (UNII: 22ADO53M6F)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:60505-6222-2	1 in 1 CARTON	10/06/2022	
1	NDC:60505-6222-1	2.5 mL in 1 BOTTLE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:60505-6222-3	2 in 1 CARTON	10/06/2022	
2		2.5 mL in 1 BOTTLE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090918	10/06/2022	

Labeler - Apotex Corp. (845263701)

Revised: 12/2023

Apotex Corp.