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 ifyou 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 2ºC to 25ºC (36ºF to 77ºF)

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

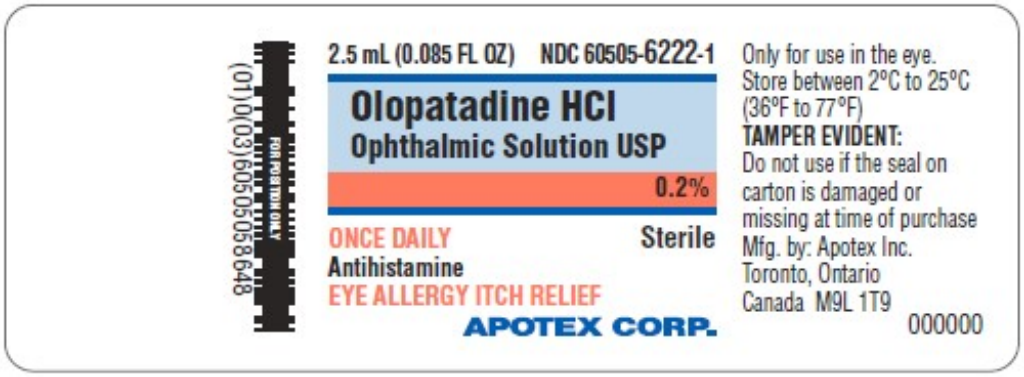
ONCE DAILY RELIEF

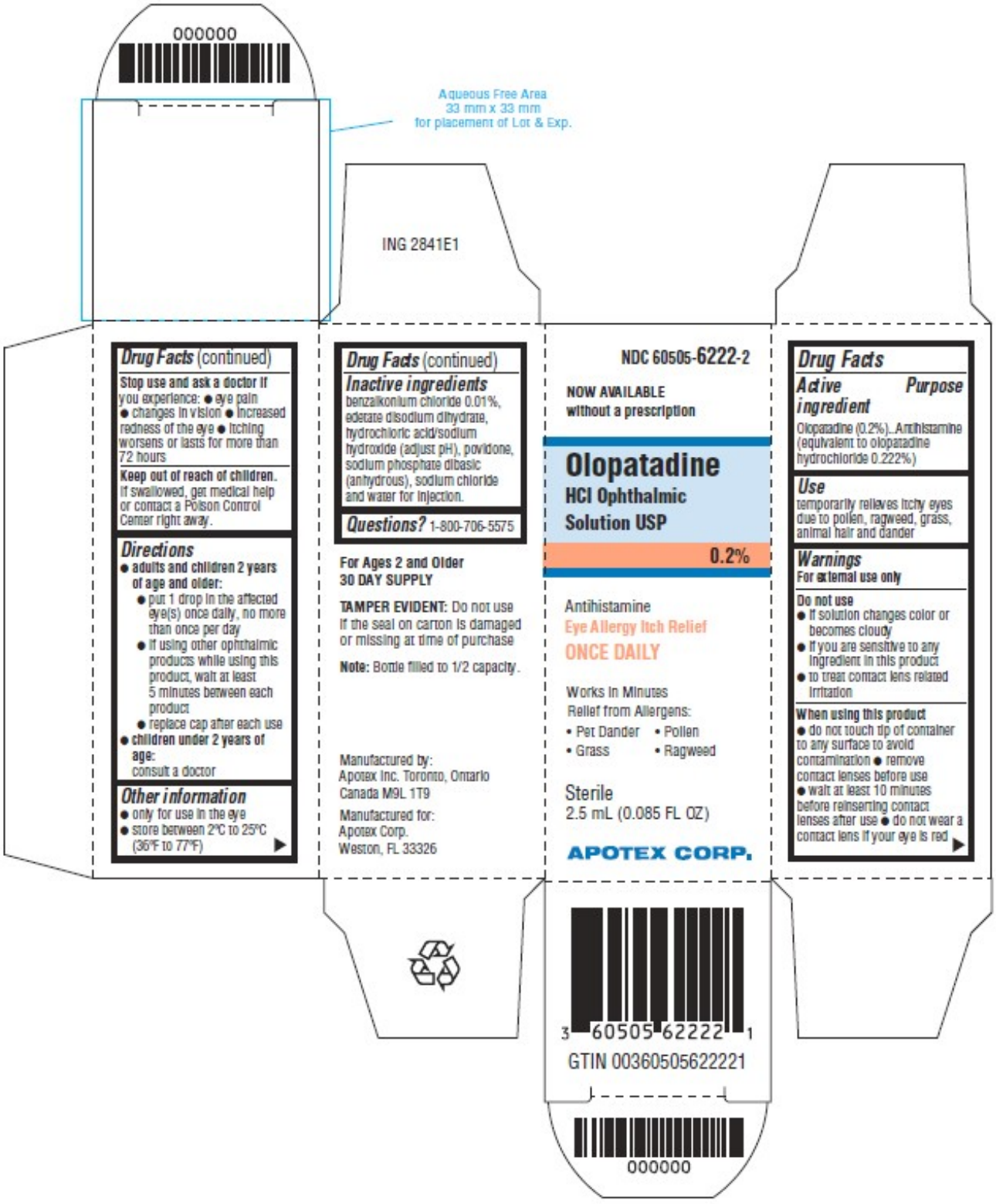
Olopatadine HCl Ophthalmic Solution, USP 0.2%

Antihistamine

Eye Allergy Itch Relief

NDC 60505-6222-2





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.