

OLOPATADINE HYDROCHLORIDE- olopatadine hydrochloride solution/ drops
Apotex Corp.

Drug Facts

Active ingredient (in each tablet)

Olopatadine (01.%) (equivalent to olopatadine hydrochloride 0.111%)

Purpose

Antihistamine and redness reliever

Uses

Temporarily relieves itchy and red 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) twice daily, every 6 to 8 hours, no more than twice 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 4°C to 25°C (39°F to 77°F)

Inactive ingredients

benzalkonium chloride 0.01%, dibasic sodium phosphate (anhydrous), hydrochloric acid and/or sodium hydroxide (to adjust pH), purified water and sodium chloride

Questions?

1-800-706-5575

Principal Display Panel

TWICE DAILY RELIEF

Olopatadine HCl Ophthalmic Solution, USP 0.1%

Antihistamine and Redness Reliever

Eye Allergy Itch & Redness Relief

NDC 60505-6221-0

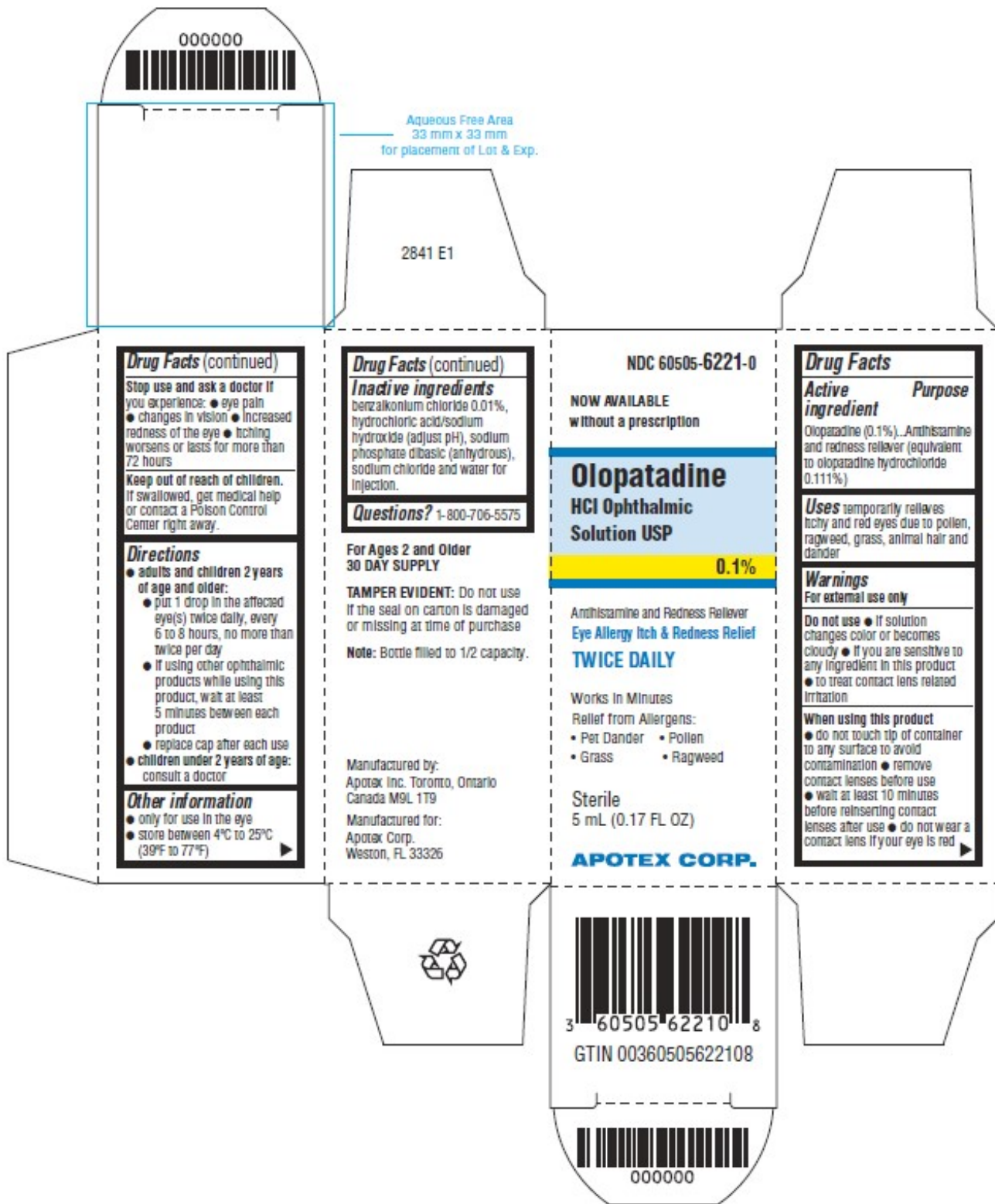
5 mL (0.17 FL OZ) NDC 60505-6221-0

Olopatadine
HCl Ophthalmic Solution USP
0.1%

TWICE DAILY Sterile
Antihistamine & Redness Reliever
Eye Allergy Itch & Redness Relief
APOTEX CORP.

Only for use in the eye.
Store between 4°C to 25°C
(39°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

(01)01(03)60505057511



OLOPATADINE HYDROCHLORIDE

olopatadine hydrochloride solution/ drops

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:60505-6221 |
| Route of Administration | OPHTHALMIC | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|-----------------|
| OLOPATADINE HYDROCHLORIDE (UNII: 2XG66W44KF) (Olopatadine - UNII:D27V6190PM) | Olopatadine | 1 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:60505-6221-0 | 1 in 1 CARTON | 10/06/2022 | |
| 1 | | 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 | ANDA078350 | 10/06/2022 | |

Labeler - Apotex Corp. (845263701)

Revised: 12/2023

Apotex Corp.