

**CHILDRENS PEDIACLEAR 8- pyrilamine maleate liquid**  
**GM Pharmaceuticals, INC**

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**Childrens PediaClear 8**

**CHILDRENS PEDIACLEAR 8**

**NDC: 58809-770-08**

**Active ingredients**

(in each 15 mL)

Pyrilamine Maleate 12.5 mg

**Purpose**

Antihistamine

**Uses**

■ temporarily relieves runny nose and alleviates sneezing, itching of the nose or throat, and itchy, watery eyes due to hay fever or other upper respiratory allergies.

**Warnings**

**Ask a doctor before use if the child has**

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma

**Ask a doctor before use if the child is**

taking sedatives or tranquilizers

**When using this product**

- marked drowsiness may occur
- sedatives and tranquilizers may increase drowsiness
- excitability may occur, especially in children

**Stop use and ask a doctor if**

new symptoms occur

**Keep out of reach of children.**

In case of overdose, get medical help or contact a Poison Control Center right away.

## **Directions**

- mL= milliliter
- use enclosed 15 mL dose cup and keep with product
- children 6 to under 12 years: 30 mL (2 dose cups) every 6 to 8 hours, not to exceed 4 doses in 24 hours, or as directed by a doctor
- children under 6 years of age: consult a doctor.

## **Other information**

- each 15 mL contains: Sodium 6 mg
- read all product information before using
- this packaging is child-resistant
- store at room temperature 20-30°C (68-86°F)

## **Inactive ingredients**

citric acid anhydrous, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate, sorbitol, sucralose

## **Questions or comments?**

Call 1-888-535-0305 9 a.m. - 5 p.m. CST.

## **PRINCIPAL DISPLAY PANEL**

NDC 58809-770-08

Children's

PediaClear

8 Eight

8 fl oz (237 mL)

TAMPER EVIDENT: DO NOT USE IF  
FOIL SEAL UNDER CAP IS BROKEN  
OR MISSING.

**RELIEVES:**

Sneezing  
Runny Nose  
Itchy, Watery Eyes  
Itchy Nose  
Itchy Throat

**CLEAN & CLEAR:**

Gluten Free  
Dye Free  
Sugar Free  
Alcohol Free

NDC 58809-770-08

Children's  
**PediaClear® 8)**

UP  
TO **8 HOUR**  
**ALLERGY RELIEF**

Pyrilamine Maleate 12.5 mg  
Antihistamine

Sneezing • Runny Nose  
Itchy, Watery Eyes  
Itchy Nose • Itchy Throat

8 fl oz (237 mL)



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COMPLETE DRUG FACTS



Distributed by:  
GM Pharmaceuticals, Inc.  
Fort Worth, TX 76118

401142-01 Rev.0523

## Drug Facts

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(in each 15 mL)**

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**Other information**

■ each 15 mL contains: **Sodium 6 mg**  
■ read all product information before using  
■ this packaging is child-resistant  
■ store at room temperature 20-30°C (68-86°F)

**Inactive ingredients**

citric acid anhydrous, glycerin, masking agent, propylene  
glycol, purified water, sodium benzoate, sodium citrate,  
sorbitol solution, sucralose

**Questions or comments?**

Call 1-888-535-0305 9 a.m. - 5 p.m. CST.

# CHILDRENS PEDIACLEAR 8

pyrilamine maleate liquid

## Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:58809-770 |
| Route of Administration | ORAL           |                    |               |

## Active Ingredient/Active Moiety

| Ingredient Name   | Basis of Strength  | Strength         |
|---|--------------------|------------------|
| <b>PYRILAMINE MALEATE</b> (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL) | PYRILAMINE MALEATE | 12.5 mg in 15 mL |

## Inactive Ingredients

| Ingredient Name                                 | Strength |
|---|----------|
| <b>ANHYDROUS CITRIC ACID</b> (UNII: XF417D3PSL) |          |
| <b>GLYCERIN</b> (UNII: PDC6A3C0OX)              |          |
| <b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)      |          |
| <b>WATER</b> (UNII: 059QF0KO0R)                 |          |
| <b>SODIUM BENZOATE</b> (UNII: OJ245FE5EU)       |          |
| <b>SODIUM CITRATE</b> (UNII: 1Q73Q2JULR)        |          |
| <b>SORBITOL</b> (UNII: 506T60A25R)              |          |
| <b>SUCRALOSE</b> (UNII: 96K6UQ3ZD4)             |          |

## Packaging

| # | Item Code        | Package Description                                   | Marketing Start Date | Marketing End Date |
|---|------------------|---|----------------------|--------------------|
| 1 | NDC:58809-770-08 | 237 mL in 1 BOTTLE; Type 0: Not a Combination Product | 08/19/2019           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M012                                     | 08/19/2019           |                    |

**Labeler** - GM Pharmaceuticals, INC (793000860)