

CHILDRENS PEDIACLEAR 8- pyrilamine maleate liquid
GM Pharmaceuticals, INC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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.

NDC 58809-770-08

LIFT HERE FOR COMPLETE DRUG FACTS

RELIEVES:

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

CLEAN & CLEAR:

- Gluten Free
- Dye Free
- Sugar Free
- Alcohol Free

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)



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

401142-01 Rev.0523

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Inactive ingredients

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

Questions or comments?
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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
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	12.5 mg in 15 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (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 final	part341	08/19/2019	

Labeler - GM Pharmaceuticals, INC (793000860)

Revised: 8/2023

GM Pharmaceuticals, INC