

CHILDRENS PEDIACLEAR PD- triprolidine hydrochloride 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 PD

CHILDREN'S PEDIACLEAR PD

NDC 58809-651-50

Drug Facts

Active ingredients (in each 2 mL)

Tripolidine HCl 1.25 mg

Purpose

Antihistamine

Uses

- temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:
- runny nose ■ itching of the nose or throat
- sneezing ■ itchy, watery eyes

Warnings

Do not exceed recommended dosage.

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

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

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

- use only with enclosed dropper
- do not use dropper for any other drug product
- mL= milliliter
- Professional Labeling: Take under guidance of health professionals.

children 6 to under 12 years of age: 2 mL every 6 hours, not to exceed 4 doses in 24 hours, or as directed by a doctor.

children 4 to under 6 years of age: 1.5 mL every 6 hours, not to exceed 4 doses in 24 hours, or as directed by a doctor.

children 2 to under 4 years of age: 1 mL every 6 hours, not to exceed 4 doses in 24 hours or as directed by a doctor.

infants 4 months to under 2 years of age: .5 mL every 6 hours, not to exceed 4 doses in 24 hours or as directed by a doctor.

Other information

- read all product information before using
- store at room temperature 20-30°C (68-86°F)

Inactive ingredients

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

Questions or comments?

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

Distributed by: GM Pharmaceuticals, Inc. Arlington, TX 76015

PRINCIPAL DISPLAY PANEL

NDC 58809-651-50

Children's

PediaClear

PD

Drops

1.69 fl oz (50 mL)

Do not use if foil seal under cap is missing or broken.

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

Distributed by:
GM Pharmaceuticals, Inc.
Arlington, TX 76015

NDC 58809-651-50

Children's PediaClearTM PD

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Triprolidine HCl.. 1.25 mg
Antihistamine

DROPS

1.69 fl oz (50 mL)

LIFT HERE FOR
COMPLETE
DRUG FACTS

Use with enclosed calibrated dropper.



This product includes professional labeling for medical professionals only.



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CHILDRENS PEDIACLEAR PD

triprolidine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58809-651
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	1.25 mg in 2 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
GLYCERIN (UNII: PDC6A3C0OX)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM BENZOATE (UNII: OJ245FE5EU)	
SODIUM CITRATE (UNII: 1Q73Q2JULR)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58809-651-50	50 mL in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product	07/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	07/01/2019	

Labeler - GM Pharmaceuticals, INC (793000860)

Revised: 7/2019

GM Pharmaceuticals, INC