TRIPROLIDINE HYDROCHLORIDE- triprolidine hydrochloride liquid Monarch PCM, LLC

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.

Triprolidine HCI

Drug Facts

Active ingredients (in each 1 mL dropperful)

Triprolidine HCI 0.938 mg

Purpose

Antihistamine

Uses

temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies:

- runny nose
- sneezing
- itching of the nose or throat
- 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
- may cause drowsiness
- sedatives and tranquilizers may increase the drowsiness effect

Stop use and ask a doctor if

new symptoms occur

Keep out of the reach of children.

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

Directions

Do not exceed recommended dosage.

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

AGE	DOSE
Childen 4 to under 6 years of age:	1 dropperful (1.0 mL) every 4 to 6 hours, not to exceed 4 doses (4.0 mL) in 24 hours, or as directed by a Doctor.
Children 2 to under 4 years of age	² / ₃ dropperful (0.67 mL) every 4 to 6 hours, not to exceed 4 doses (2.67 mL) in 24 hours, or as directed by a Doctor.
Infants 4 months to under 2 years of age	¹/₃ dropperful (0.33 mL) every 4 to 6 hours, not to exceed 4 doses (1.33 mL) in 24 hours, or as directed by a Doctor.

Other Information

- store at room temperature 15-30°C (59-86°F)
- Tamper evident by foil seal under cap. Do not use if foil seal is missing or broken.

Inactive ingredients

bubble gum flavor, citric acid, glycerin, methylparaben, monoammonium glycyrrhizinate, potassium citrate, potassium sorbate, propylene glycol, propylparaben, purified water, sucralose

Questions? Comments?

Call 1-844-696-6627 9 a.m. - 5 p.m. CST.

PRINCIPAL DISPLAY PANEL - 30 mL Bottle Carton

Do not use if foil seal under cap is missing or broken.
Usual Dosage:
See attached labeling for complete product information.

KEEP OUT OF REACH OF CHILDREN.

This product includes professional labeling for medical practioners only.

Manufactured by:

Monarch PCM, LLC. Fort Worth, TX 76118

Monarch Do not use if foil seal LIFT HERE FOR under cap is missing or COMPLETE DRUG FACTS PCM, LLC * broken. NDC 70154-113-30 Usual Dosage: See attached labeling for **Triprolidine HCI** complete product information. **Antihistamine** store at °30-15C (°86-68F) Each dropperful (1 mL) KEEP OUT OF REACH contains: 8 OF CHILDREN. Triprolidine HCI0.938 mg This product includes professional Sugar-Free • Dye-Free labeling for medical practioners only. Alcohol Free Manufactured by: **Bubble Gum Flavor** Monarch PCM, LLC. 3 1 fl oz (30 mL) Fort Worth, TX 76118

Drug Facts Active ingredient Purpose (in each 1 mL dropperful) Triprolidine HCI 0.938 mg..... temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies: ■runny nose ■ itching of the nose or throat ■ itchy, watery eyes ■ sneezing 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 ■ may cause drowsiness ■ 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 do not exceed recommended dosage. ■ use only with enclosed dropper ■ do not use enclosed dropper for any other drug product ■ mL= milliliter ■ Professional Labeling: Take under guidance of Health

CALIBRATED DROPPER ENCLOSED.	
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Age	Dose
children 4 to under 6 years of age:	1 dropperful (1.0 mL) every 4 to 6 hours, not to exceed 4 doses (4.0 mL) in 24 hours, or as directed by a Doctor.
children 2 to under 4 years of age:	2/3 dropperful (0.67 mL) every 4 to 6 hours, not to exceed 4 doses (2.67 mL) in 24 hours, or as directed by a Doctor.
infants 4 months to under 2 years of age:	1/3 dropperful (0.33 mL) every 4 to 6 hours, not to exceed 4 doses (1.33 mL) in 24 hours, or as directed by a Doctor.

Other information

Professionals.

- store at room temperature 15-30°C (59-86°F)
- Tamper evident by foil seal under cap. Do not use if foil seal is missing or broken.

Inactive ingredients

bubble gum flavor, citric acid, glycerin, methylparaben, monoammonium glycyrrhizinate, potassium citrate, potassium sorbate, propylene glycol, propylparaben, purified water, sucralose

Questions or comments?

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TRIPROLIDINE HYDROCHLORIDE

triprolidine hydrochloride liquid

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:70154-204 Route of Administration ORAL

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
TRIPROLIDINE HYDROCHLORIDE (UNII: YAN7R5L890) (TRIPROLIDINE - UNII: 2L8T9S52QM)	TRIPROLIDINE HYDROCHLORIDE	0.938 mg in 1 mL	

Inactive Ingredients			
Ingredient Name	Strength		
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)			
GLYCERIN (UNII: PDC6A3C0OX)			
METHYLPARABEN (UNII: A2I8C7HI9T)			
POTASSIUM SORBATE (UNII: 1VPU26JZZ4)			
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)			
PROPYLPARABEN (UNII: Z8IX2SC1OH)			
WATER (UNII: 059QF0KO0R)			
SUCRALOSE (UNII: 96K6UQ3ZD4)			
POTASSIUM CITRATE (UNII: EE90ONI6FF)			
AMMONIUM GLYCYRRHIZINATE TRIHYDRATE (UNII: 78NEL3149I)			

ı	Packaging			
	# Item Code	Package Description	Marketing Start Date	Marketing End Date
	1 NDC:70154-204-30	30 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	M012	08/19/2019	10/31/2024

Labeler - Monarch PCM, LLC (080000294)

Revised: 1/2023 Monarch PCM, LLC