

MICLARA LQ- triprolidine hydrochloride liquid

Key Therapeutics

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.

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MICLARA LQ LIQUID

Drug Facts

Active ingredients

(in each 5 mL teaspoonful) Triprolidine HCl 1.25 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.

Do not use this product if you have

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- trouble urinating due to an enlarged prostate gland

Ask a doctor before use

if you are taking sedatives or tranquilizers.

When using this product

- may cause excitability especially in children
- may cause drowsiness
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- be careful when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- new symptoms occur

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children.

In case of accidental overdose seek professional help or contact a Poison Control Center immediately.

Directions

Do not exceed recommended dosage.

Adults and children

12 years of age and older:

Children 6 to under 12 years of age:

2 teaspoonfuls (10 mL) every 4 to 6 hours, not to exceed

8 teaspoonfuls (40mL) in 24-hour

period or as directed by a doctor.

1 teaspoonful (5 mL) every 4 to 6 hours, not to exceed 4 teaspoonfuls (20mL) in a 24-hour period or as directed by a doctor.

Children under 6 years of age: Consult a doctor

Other information

Store at 59° - 86°F (15° - 30°C)

Inactive ingredients

Bubble gum flavor, citric acid, methylparaben, monoammonium glycyrrhizinate, potassium citrate, propylene glycol, propylparaben, purified water, sorbitol, sucralose.

Questions? Comments?

Serious side effects associated with use of this product May be reported to this number. Call 1-888-981-8337

Mon - Fri (8 a.m. to 5 p.m. CST)

PRINCIPAL DISPLAY PANEL

NDC 70868-730-16 Miclara LQ

Antihistamine

Each 5 mL (1 teaspoonful) contains: Triprolidine HCl 1.25 mg.....Antihistamine

Bubble Gum Flavor

Dye Free - Sugar Free - Alcohol Free

16 fl oz. (473 mL)

Distributed by:

Key Therapeutics, LLC

Flowood, MS 39232

Iss. 03/20

	Drug Facts Active ingredient (in each 5 mL teaspoonful) Triprolidine HCl 1.25 mg.....Antihistamine Purpose Antihistamine Uses temporarily relieves these symptoms due to hay fever (allergic rhinitis) or other upper respiratory allergies: ■ runny nose ■ sneezing ■ itching of nose or throat ■ itchy, watery eyes Warnings Do not exceed recommended dosage. Ask a doctor before use if you have ■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma ■ trouble urinating due to an enlarged prostate gland Ask a doctor before use if you are taking sedatives or tranquilizers. In case of accidental overdose, seek professional help or contact a Poison Control center immediately. When using this product ■ excitability may occur, especially in children ■ may cause drowsiness ■ avoid alcoholic drinks ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ be careful when driving a motor vehicle or operating machinery	Drug Facts (continued) Stop use and ask a doctor if ■ new symptoms occur If pregnant or breast-feeding, ask a health professional before use. Keep out of the reach of children Directions Do not exceed recommended dosage. <table border="1"> <thead> <tr> <th>AGE</th> <th>DOSE</th> </tr> </thead> <tbody> <tr> <td>Adults and children 12 years of age and older:</td> <td>2 teaspoonful (10mL) every 4 to 6 hours, not to exceed 8 teaspoonfuls (40mL) in a 24-hour period or as directed by a doctor</td> </tr> <tr> <td>Children 6 to under 12 years of age:</td> <td>1 teaspoonful (5 mL) every 4 to 6 hours, not to exceed 4 teaspoonfuls (20mL) in a 24-hour period or as directed by a doctor</td> </tr> <tr> <td>Children under 6 years of age:</td> <td>Consult a doctor</td> </tr> </tbody> </table> Other information Store at 59° - 86°F (15° - 30°C) Inactive ingredients Bubble gum flavor, citric acid, methylparaben, monoammonium glycrhizinate, potassium citrate, propylene glycol, polyparaben, purified water, sorbitol, sucralose Questions? Comments? Serious side effects associated with use of this product may be reported to this number. 1-888-981-8337 Mon. - Fri. (8 a.m. to 5 p.m. CST). Iss. 03/20	AGE	DOSE	Adults and children 12 years of age and older:	2 teaspoonful (10mL) every 4 to 6 hours, not to exceed 8 teaspoonfuls (40mL) in a 24-hour period or as directed by a doctor	Children 6 to under 12 years of age:	1 teaspoonful (5 mL) every 4 to 6 hours, not to exceed 4 teaspoonfuls (20mL) in a 24-hour period or as directed by a doctor	Children under 6 years of age:	Consult a doctor
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Lot: Exp. Date:										

MICLARA LQ

triprolidine hydrochloride liquid

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70868-730
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRIPRO LIDINE HYDRO CHLORIDE (UNII: YAN7R5L890) (TRIPRO LIDINE - UNII:2L8 T9 S52QM)	TRIPRO LIDINE HYDRO CHLORIDE	1.25 mg in 5 mL

Inactive Ingredients

Ingredient Name	Strength
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	

METHYL PARABEN (UNII: A2I8C7H9T)	
AMMONIUM GLYCYRRHIZATE (UNII: 3VRD35U26C)	
POTASSIUM CITRATE (UNII: EE90ONI6FF)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
PROPYL PARABEN (UNII: Z8IX2SC1OH)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics			
Color		Score	
Shape		Size	
Flavor	BUBBLE GUM	Imprint Code	
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70868-730-16	473 mL in 1 BOTTLE; Type 0: Not a Combination Product	05/15/2020	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	05/15/2020	

Labeler - Key Therapeutics (080318791)