**MICLARA DM- dextromethorphan hbr, phenylephrine hcl, triprolidine hcl 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 DM**

**MICLARA LQ LIQUID**

**Drug Facts**

**Active ingredients**

**(in each 5 mL teaspoonful)**

| | |
|---|---|
| Dextromethorphan HBr | 20mg |
| Phenylephrine HCl | 10mg |
| Triprolidine HCl | 2.5 mg |

**Purpose**

**Uses**

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

- cough due to minor throat or bronchial irritation
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes
- nasal congestion
- reduces swelling of nasal passages

**Warnings**

**Do not exceed recommended dosage.**

**Do not use this product**

If you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before giving this product.

**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
- heart disease
- high blood pressure
- a cough that occurs with too much phlegm (mucus)
- a persistent chronic cough such occurs with smoking, asthma, chronic bronchitis, or emphysema

**Ask a doctor before use**

**if you are taking sedatives or tranquilizers.**

**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

**Stop use and ask a doctor if**

- new symptoms occur
- nervousness, dizziness, or sleeplessness occur
- Cough or nasal congestion lasts for more than 1 week, tends to recur or is accompanied by a fever, rash, or persistent headache. These could be signs of a serious condition.

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.**

| **Age** | **Dose** |
|---|---|
| Adults and children 12 years of age and older: | 1 teaspoonful (5mL) every 4 hours, not to exceed 4 teaspoonfuls (20mL) in a 24-hour period or as directed by a doctor |
| **Children 6 to under 12 years of age:** | ½ teaspoonful (2.5mL) every 4 hours, not to exceed 2 teaspoonfuls (10mL) 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

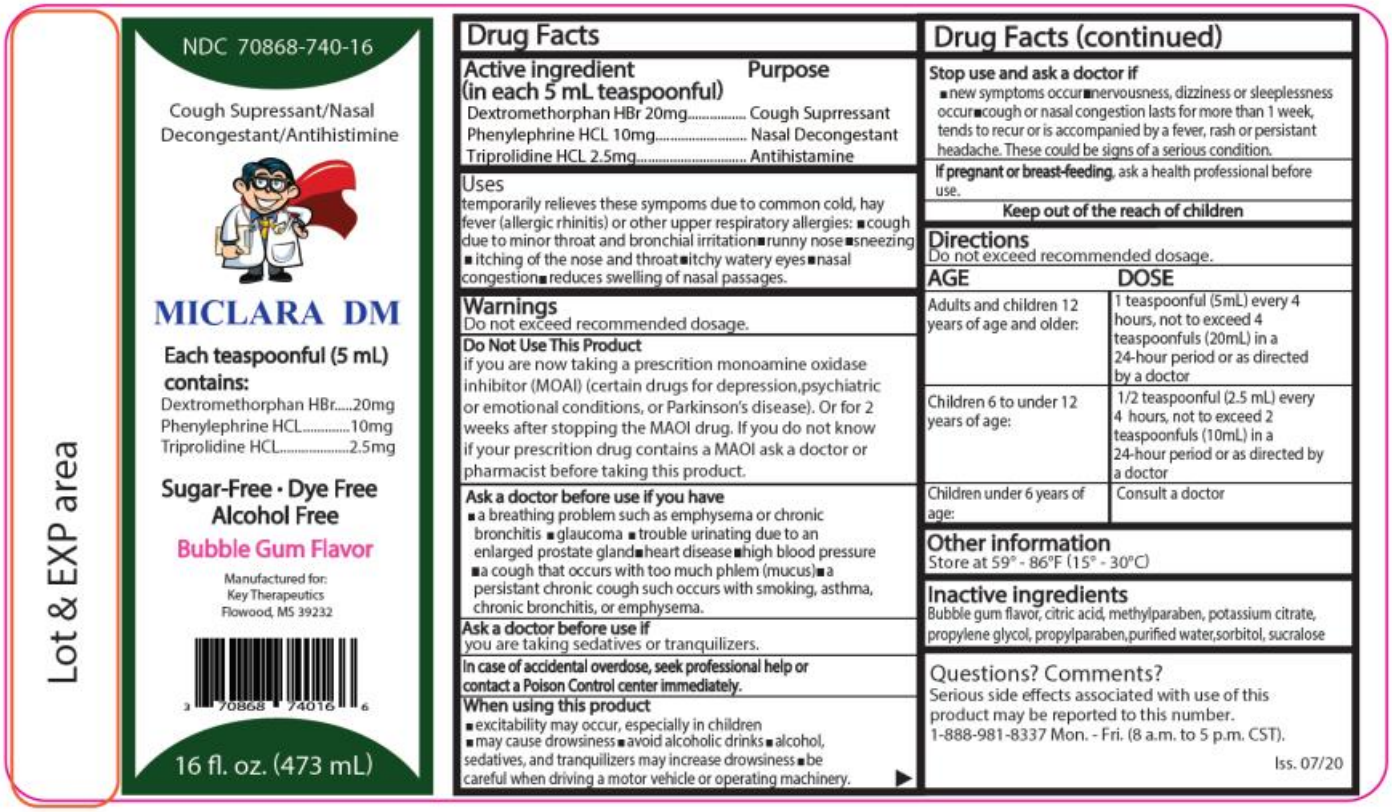
Bubble gum flavor, citric acid, methylparaben, potassium citrate, propylene glycol, propylparaben, purified water, sorbitol, sucralose.

## 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 70868-740-16
MICLARA DM
Bubble gum flavor
16 fl oz (473 mL)




## MICLARA DM

dextromethorphan hbr, phenylephrine hcl, triprolidine hcl liquid

### Product Information

| | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:70868-740 |
| **Route of Administration** | ORAL | | |

## Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|---|---|
| **DEXTROMETHORPHAN HYDROBROMIDE** (UNII: 9D2RTI9KYH) (DEXTROMETHORPHAN - UNII:7355X3ROTS) | DEXTROMETHORPHAN HYDROBROMIDE | 20 mg in 5 mL |
| **PHENYLEPHRINE HYDROCHLORIDE** (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV) | PHENYLEPHRINE HYDROCHLORIDE | 10 mg in 5 mL |
| **TRIPROLIDINE HYDROCHLORIDE** (UNII: YAN7R5L890) (TRIPROLIDINE - UNII:2L8T9S52QM) | TRIPROLIDINE HYDROCHLORIDE | 2.5 mg in 5 mL |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| **CITRIC ACID MONOHYDRATE** (UNII: 2968PHW8QP) | |
| **METHYLPARABEN** (UNII: A2I8C7HI9T) | |
| **POTASSIUM CITRATE** (UNII: EE90ONI6FF) | |
| **PROPYLENE GLYCOL** (UNII: 6DC9Q167V3) | |
| **PROPYLPARABEN** (UNII: Z8IX2SC1OH) | |
| **WATER** (UNII: 059QF0KO0R) | |
| **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:70868-740-16 | 473 mL in 1 BOTTLE; Type 0: Not a Combination Product | 09/01/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 09/01/2020 | |

## Labeler - Key Therapeutics (080318791)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| TG United | | 172837085 | manufacture(70868-740) |

Revised: 1/2022

Key Therapeutics