**MAXIFED TR- pseudoephedrine hydrochloride and triprolidine hydrochloride tablet**
**MCR American 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.*

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**Maxifed TR Tablets**

***Drug Facts***

| ***Active Ingredients (in each tablet)*** | ***Purpose*** |
|---|---|
| Pseudoephedrine HCl 30 mg | Nasal Decongestant |
| Triprolidine HCl 1.25 mg | Antihistamine |

**Uses**

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

- 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 taking this product.

**Ask a doctor before use if you have**

- a breathing problem such as emphysema or chronic bronchitis
- glaucoma
- heart disease
- high blood pressure
- thyroid disease
- diabetes mellitus
- difficulty in urination due to enlargement of the prostate gland

**Ask a doctor or pharmacist before use if you are taking sedatives or tranquilizers**

**When using this product**

- excitability may occur, especially in children
- may cause drowsiness
- alcohol, sedatives and tranquilizers may increase drowsiness effect
- avoid alcoholic beverages

- use caution when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if**

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or are accompanied by fever
- new symptoms occur

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

**Keep out of 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 over: | 2 tablets every 4-6 hours, not to exceed 8 tablets in 24 hours, or as directed by a doctor |
| Children 6 to under 12 years of age: | 1 tablet every 4-6 hours, not to exceed 4 tablets in 24 hours, or as directed by a doctor |
| Children under 6 years of age: | Consult a doctor. |

**Inactive ingredients**

Magnesium stearate, microcrystalline cellulose, sodium starch glycolate

**Questions or Comments?**

Call 1-352-754-8587

**PRINCIPAL DISPLAY PANEL - 100 Tablet Bottle Label**

NDC 58605-106-01

Maxifed TR Tablets

Nasal Decongestant • Antihistamine

Each tablet contains:

Pseudoephedrine HCl
30 mg
Triprolidine HCl
1.25 mg

Store at 59°-86°F (15°-30°C)
[see USP Controlled Room Temperature].

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

Manufactured for:
MCR American Pharmaceuticals, Inc.
Brooksville, FL 34604

100 tablets

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N 3 58605 10601 7

Lot :
Exp. Date:

## *Drug Facts* (continued)

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Rev. 05/20

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Lift Here

**MAXIFED TR**

pseudoephedrine hydrochloride and triprolidine hydrochloride tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:58605-106 |
| **Route of Administration** | ORAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **Pseudoephedrine Hydrochloride** (UNII: 6V9V2RYJ8N) (Pseudoephedrine - UNII:7CUC9DDI9F) | Pseudoephedrine Hydrochloride | 30 mg |
| **Triprolidine Hydrochloride** (UNII: YAN7R5L890) (Triprolidine - UNII:2L8T9S52QM) | Triprolidine Hydrochloride | 1.25 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **Magnesium Stearate** (UNII: 70097M6I30) | |
| **Microcrystalline Cellulose** (UNII: OP1R32D61U) | |
| **SODIUM STARCH GLYCOLATE TYPE A POTATO** (UNII: 5856J3G2A2) | |

| Product Characteristics | | | |
|---|---|---|---|
| **Color** | WHITE | **Score** | 2 pieces |
| **Shape** | OVAL | **Size** | 16mm |
| **Flavor** | | **Imprint Code** | TR |
| **Contains** | | | |

| Packaging | | | | |
|---|---|---|---|---|
| **#** | **Item Code** | **Package Description** | **Marketing Start Date** | **Marketing End Date** |
| **1** | NDC:58605-106-01 | 100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product | 08/01/2020 | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC MONOGRAPH FINAL | part341 | 08/01/2020 | |

## Labeler - MCR American Pharmaceuticals, Inc. (783383011)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| MCR American Pharmaceuticals, Inc. | | 783383011 | MANUFACTURE(58605-106) |