**NAPHAZOLINE HYDROCHLORIDE- naphazoline hydrochloride solution/ drops**
**Doral Pharmamedics Inc DBA AG Marin Pharmaceuticals**

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## Naphazoline hydrochloride 0.05%

Naphazoline hydrochloride 0.05% v/v. Purpose: Nasal decongestant

Keep out of reach of children. In case of accidental overdose, get medical help or contact a Poison Control Center right away.

Stop using this product after 3 days.

If symptoms persist, stop, and consult a doctor.

Benzalkonium chloride, purified water, sodium bisulfite, sodium chloride, and sodium citrate.

For the temporary relief of nasal congestion due to the common cold, hay fever, or sinusitis.

Temporarily relieves a stuffy nose.

Helps clear nasal passages.

Use for the temporary relief of nasal congestion due to the common cold, hay fever, or sinusitis.

Adults and children 12 years of age and over: 1 or 2 drops in each nostril not more often than every 6 hours. Do not give to children under 12 years of age unless directed by a doctor.

Do not exceed recommended dosage.

This product may cause temporary discomfort such as burning, stinging, sneezing, or an increase in nasal discharge.

The use of this container by more than one person may spread infection.

Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor.

Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

Do not use this product in children under 12 years of age because it may cause sedation if swallowed.

When using this product avoid contact with the eyes.

If you are pregnant or breast-feeding consult a health care professional before using this product.

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 are uncertain whether your prescription drug contains an MAOI, consult a health professional before taking this product.

Do not use this product for more than 3 days. Use only as directed. Frequent or prolonged use may cause nasal congestion to recur or worsen. If symptoms persist, consult a doctor.

Do not use this product if you have heart disease, high blood pressure, thyroid disease, diabetes, or difficulty in urination due to enlargement of the prostate gland unless directed by a doctor.

Do not use this product in children under 12 years of age because it may cause sedation if swallowed.

Do not use this product in a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor.

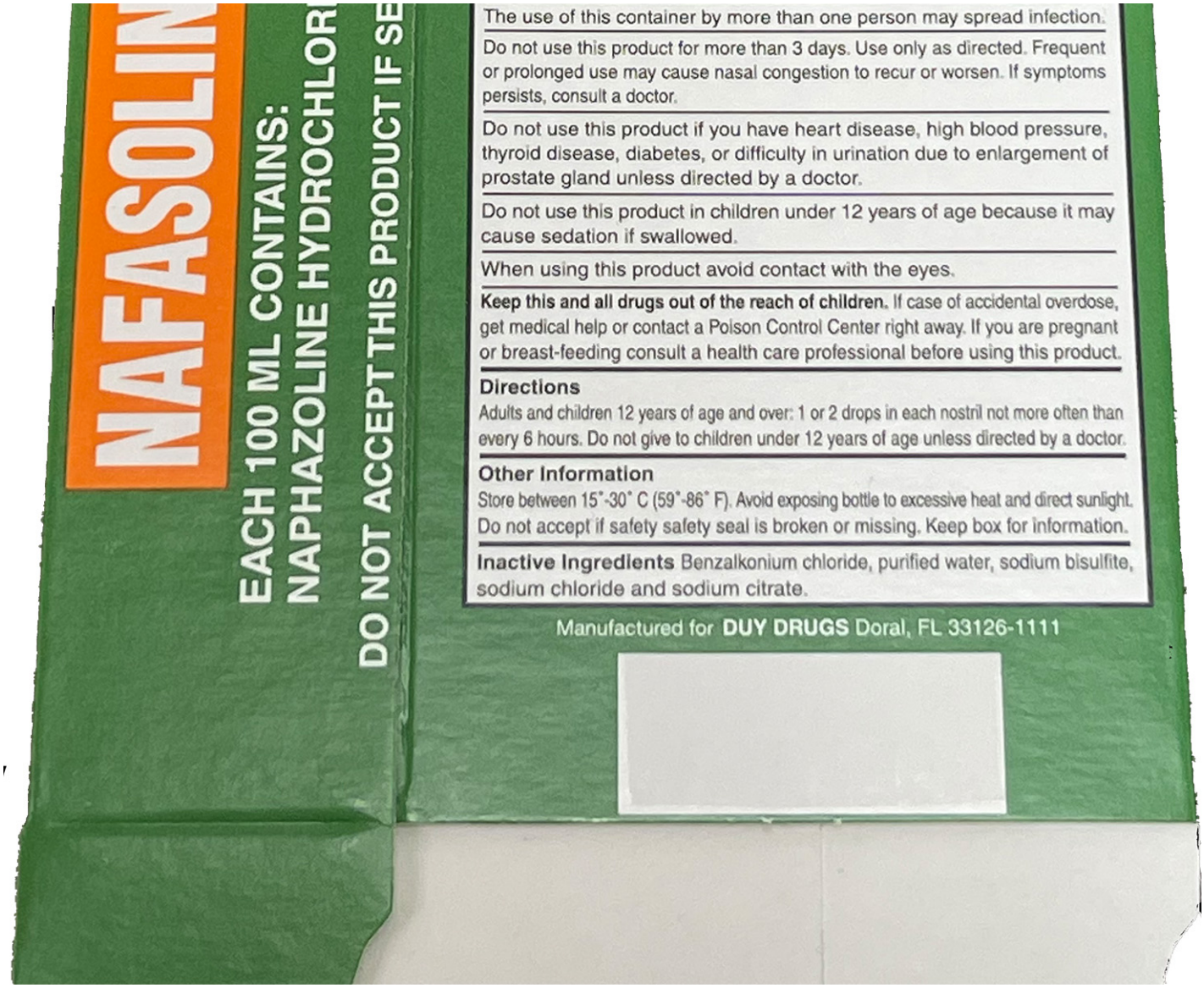
This product is for nasal use only.

When using this product avoid contact with the eyes. In case of contact with eyes, rinse eyes thoroughly with water.

Naphazoline hydrochloride 0.05% nasal drops are indicated for the temporary relief of nasal congestion due to the common cold, hay fever, or sinusitis. Temporarily relieves a stuffy nose. Helps clear nasal passages.

Principal Display Panel

0.5 FL. OZ NDC: 12539-144-08




# NAPHAZOLINE HYDROCHLORIDE

naphazoline hydrochloride solution/ drops

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG | **Item Code (Source)** | NDC:12539-145 |
| **Route of Administration** | NASAL | | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **NAPHAZOLINE HYDROCHLORIDE** (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV) | NAPHAZOLINE HYDROCHLORIDE | 0.376 mg in 100 mg |

| Inactive Ingredients | |
|---|---|
| **Ingredient Name** | **Strength** |
| **WATER** (UNII: 059QF0KO0R) | 95.624 mg in 100 mg |

| | |
|---|---|
| **SODIUM BISULFITE** (UNII: TZX5469Z6I) | 1 mg in 100 mg |
| **BENZALKONIUM CHLORIDE** (UNII: F5UM2KM3W7) | 1 mg in 100 mg |
| **SODIUM CITRATE** (UNII: 1Q73Q2JULR) | 1 mg in 100 mg |
| **SODIUM CHLORIDE** (UNII: 451W47IQ8X) | 1 mg in 100 mg |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| **1** | NDC:12539-145-09 | 1 in 1 CARTON | 02/28/2025 | |
| **1** | NDC:12539-145-08 | 15000 mg in 1 BOTTLE, DROPPER; Type 0: Not a Combination Product | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC Monograph Drug | M012 | 02/28/2025 | |

## Labeler - Doral Pharmamedics Inc DBA AG Marin Pharmaceuticals (076007996)

## Registrant - Doral Pharmamedics Inc DBA AG Marin Pharmaceuticals (076007996)

## Establishment

| Name | Address | ID/FEI | Business Operations |
|---|---|---|---|
| DEXTRUM LABORATORIES INC. | | 007392322 | manufacture(12539-145) |

Revised: 2/2025 Doral Pharmamedics Inc DBA AG Marin Pharmaceuticals