

NAFASOLINA- naphazoline hydrochloride solution/ drops
Doral Pharmamedics Inc DBA AG Marin Pharmaceuticals

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.

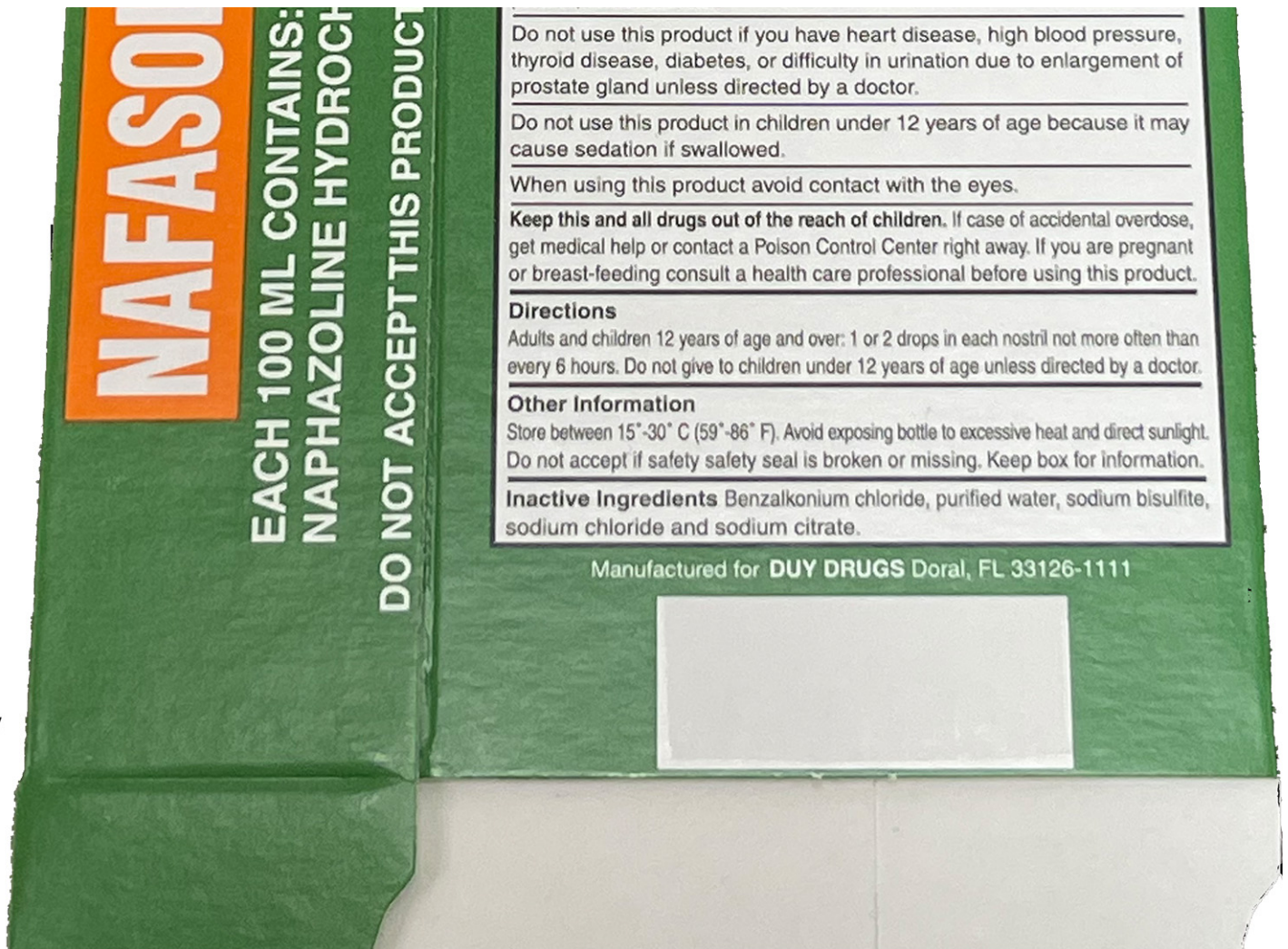
Do not use this product in a child who has heart disease, high blood pressure, thyroid disease, or diabetes unless directed by a doctor.

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: 12539-146-02

NAFASOLINA			
naphazoline hydrochloride solution/ drops			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:12539-146
Route of Administration	NASAL		
Active Ingredient/Active Moiety			
	Ingredient Name	Basis of Strength	Strength
	NAPHAZOLINE HYDROCHLORIDE (UNII: MZ1131787D) (NAPHAZOLINE - UNII:H231GF11BV)	NAPHAZOLINE HYDROCHLORIDE	50 mg in 100 mL
Inactive Ingredients			
	Ingredient Name	Strength	
	WATER (UNII: 059QF0KO0R)	95.624 mg in 100 mL	
	SODIUM BISULFITE (UNII: TZX5469Z6I)	1 mg in 100 mL	

BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	1 mg in 100 mL
SODIUM CITRATE (UNII: 1Q73Q2JULR)	1 mg in 100 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	1 mg in 100 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:12539-146-02	1 in 1 CARTON	03/20/2025	
1	NDC:12539-146-01	14.7868 mL 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	03/20/2025	

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(12539-146)

Revised: 3/2025

Doral Pharmamedics Inc DBA AG Marin Pharmaceuticals