NAFASOLINA- naphazoline hydrochloride solution/ drops
DUY DRUGS, 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.

Naphazoline hydrochloride 0.05% v/v

Active Ingredient(s)

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

Purpose

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

Temporarily relieves stuffy nose.

Helps clear nasal passages.

Use

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

Warnings

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.

Do not use

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.

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.

Keep out of reach of children.

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

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

Directions

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.

Other information

Store between 15°-30°C (59°-86°F).

Avoid exposing bottle to excessive heat and direct sunlight.

Do not accept this product if safety seal is broken or missing.

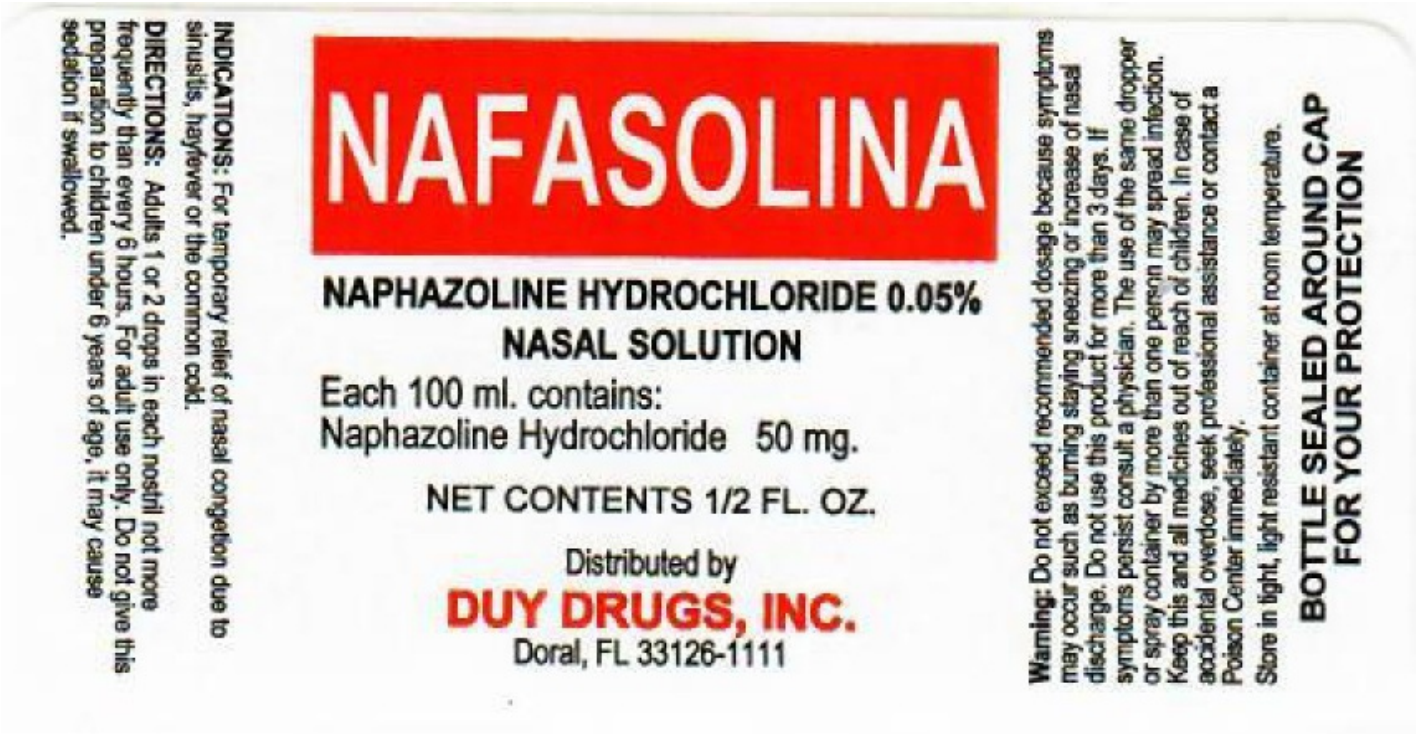
Keep box for information.

Inactive ingredients

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

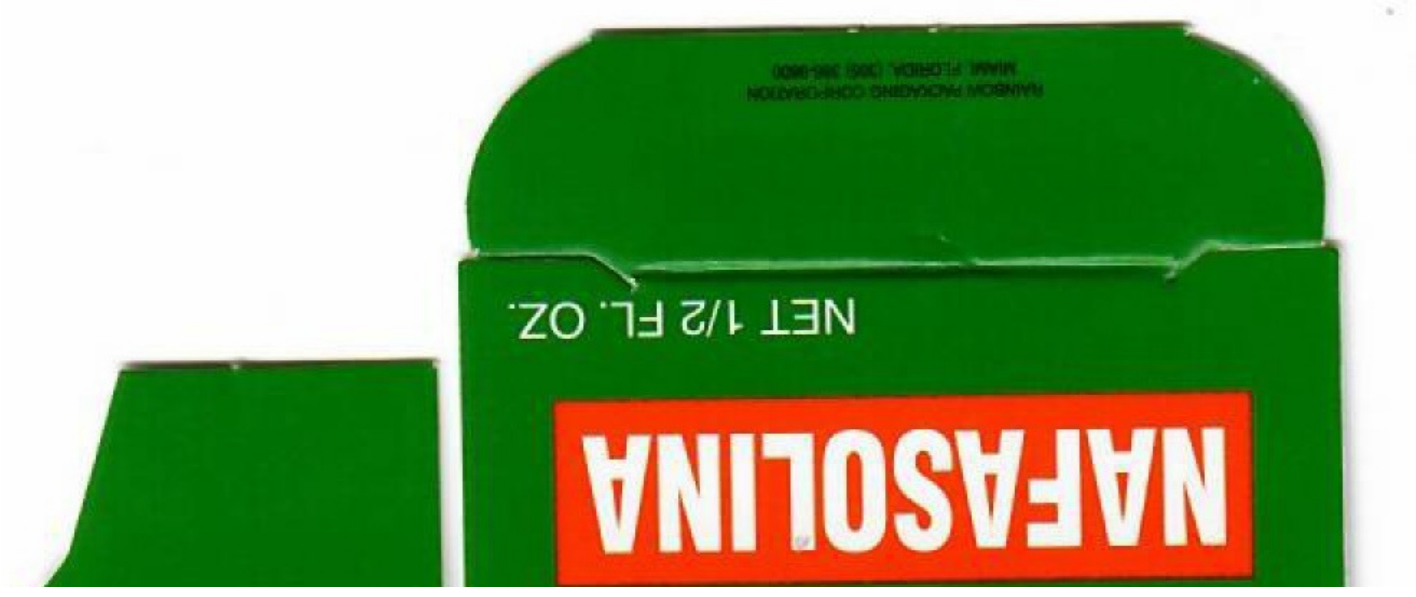
Package Label - Principal Display Panel

0.5 FL. OZ NDC: 48462-001-01



Drug Facts Panel on Outer Box

0.5 FL. OZ NDC: 48462-001-02



NAFASOLINA

EACH 100 ML CONTAINS:
NAPHAZOLINE HYDROCHLORIDE 50 MG.

DO NOT ACCEPT THIS PRODUCT IF SEAL IS BROKEN.

NAFASOLINA

DRUG FACTS

Active Ingredient
Naphazoline hydrochloride 0.05%

Purpose
Nasal decongestant

Uses For the temporary relief of nasal congestion due to the common cold, hay fever or sinusitis. Temporarily relieves stuffy nose. Helps clear nasal passages.

Warnings

Do not exceed the 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 persists, 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 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.

Keep this and all drugs out of the reach of children. If case of accidental overdose, get medical help or contact a Poison Control Center right away. If you are pregnant or breast-feeding consult a health care professional before using this product.

Directions

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.

Other Information

Store between 15°-30° C (59°-86° F). Avoid exposing bottle to excessive heat and direct sunlight. Do not accept if safety safety seal is broken or missing. Keep box for information.

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

Distributed by **DUY DRUGS** Doral, FL 33126-1111

Name of Product Outer box

0.5 FL. OZ NDC: 48462-001-02

NAFASOLINA

naphazoline hydrochloride solution/ drops

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:48462-001
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
SODIUM CHLORIDE (UNII: 451W47IQ8X)	1 mg in 100 mg
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	1 mg in 100 mg
SODIUM BISULFITE (UNII: TZX5469Z6I)	1 mg in 100 mg
WATER (UNII: 059QF0KO0R)	95.624 mg in 100 mg
SODIUM CITRATE (UNII: 1Q73Q2JULR)	1 mg in 100 mg

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:48462-001-02	13310 in 1 CARTON	02/15/2021	
1	NDC:48462-001-01	13310 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 final	part341	02/15/2021	

Labeler - DUY DRUGS, INC (162053206)

Registrant - DUY DRUGS, INC (162053206)

Establishment

Name	Address	ID/FEI	Business Operations
DEXTRUM LABORATORIES INC.		007392322	manufacture(48462-001)

Establishment

Name	Address	ID/FEI	Business Operations
DUY DRUGS, INC		162053206	label(48462-001)

Revised: 2/2021 DUY DRUGS, INC