EXTRA STRENGTH SINUS RELIEF NASAL DECONGESTANT- phenylephrine hydrochloride spray
CARDINAL HEALTH

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.

LEADER Extra Strength Sinus Relief Phenylephrine Hydrochloride 1.0% Nasal Decongestant 1 FL OZ

Active ingredients

Phenylephrine Hydrochloride 1.0 %

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion:
- due to common cold
- due to hay fever or other upper respiratory allergies (allergic rhinitis)
- temporarily relieves stuffy nose.
- helps clear nasal passages; shrinks swollen membranes
- temporarily restores freer breathing through the nose
- helps decongest sinus openings and passages; temporarily relieves sinus congestion and pressure

Warnings

Do Not Use

If you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- difficulty in urination due to enlargement of the prostate gland

When using this product

- **do not exceed recommended dosage**
- do not use for more than 3 days. Use only as directed.

Frequent or prolonged use may cause nasal congestion to recur or worsen

- temporary discomfort may occur such as burning, stinging, sneezing and increase in nasal discharge
- use of this container by more than one person may spread infection

Stop use and ask a doctor if

symptoms persist for more than 3 days.

If pregnant or breast-feeding

ask a health professional before use.

Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center right away 1-800-222-1222

Directions

- Use only as directed
- to spray, squeeze bottle quickly and firmly
- **adults and children 12 years older:** 2 or 3 sprays in each nostril not more often than every 4 hours.
- **children under 12 years :** ask a doctor

Other information

- store at room temperature
- Protect from light.

Inactive ingredients

anhydrous citric acid, benzalkonium chloride, benzyl alcohol, purified water, sodium chloride, sodium citrate

Questions

1-866-467-2748

Principal Display

LEADER

NDC 70000-0132-1

COMPARE TO NEO-SYNEPHRINE® EXTRA STRENGTH active ingredient

Extra Strength

Sinus Relief

Phenylephrine hydrochloride 1.0 %

Nasal Decongestant

Fast Relief Of:

Sinus Congestion & Pressure

Colds, Allergies

1 FL OZ (30 mL)

* This product is not manufactured or distributed by Foundation Consumer Healthcare LLC owner of the registered trademark Neo-Synephrine® Extra Strength.

IMPORTANT: Keep this carton for future reference on full labeling.

Do not use if printed seal over cap is torn or missing

Cardinal Health™

DISTRIBUTED BY CARDINAL HEALTH

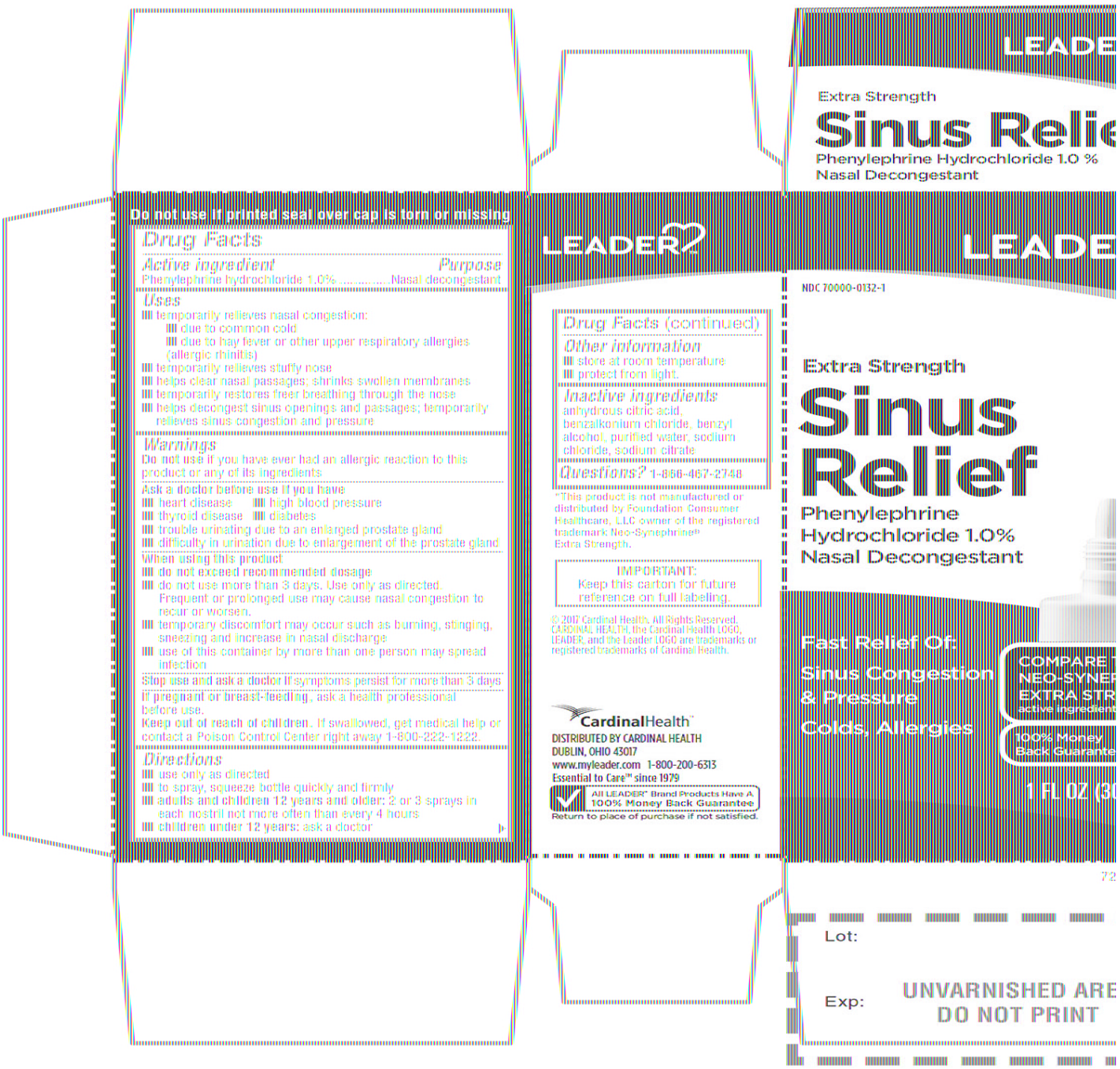
DUBLIN, OHIO 43017

www.myleader.com

1-800-200-6313

Essential to care™ since 1979

* This product is not manufactured or distributed by Foundation Consumer Healthcare LLC owner of the registered trademark Neo-Synephrine® Extra Strength.



EXTRA STRENGTH SINUS RELIEF NASAL DECONGESTANT

phenylephrine hydrochloride spray

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:70000-0132
Route of Administration	NASAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	1 g in 100 mL

Inactive Ingredients

Ingredient Name	Strength
ANHYDROUS CITRIC ACID (UNII: XF417D3PSL)	
BENZALKONIUM CHLORIDE (UNII: F5UM2KM3W7)	
BENZYL ALCOHOL (UNII: LKG8494WBH)	
WATER (UNII: 059QF0KO0R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
SODIUM CITRATE, UNSPECIFIED FORM (UNII: 1Q73Q2JULR)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0132-1	1 in 1 CARTON	06/06/2017	
1		30 mL in 1 BOTTLE, SPRAY; 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	06/06/2017	

Labeler - CARDINAL HEALTH (063997360)

Revised: 10/2023 CARDINAL HEALTH