NASOPEN PE- phenylephrine hydrochloride, thonzylamine hydrochloride liquid
GM 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.

Nasopen PE

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NDC 58809-729-04

Tamper evident by foil seal under cap.

Do not use if foil seal is broken or missing.

Supplied in a tight, light-resistant container with a child-resistant cap.

Distributed by: GM Pharmaceuticals, Inc.

Arlington, TX 76015

Drug Facts

Active ingredients (in each 15 mL (TBSP))

Phenylephrine HCl 10 mg

Thonzylamine HCl 50 mg

Purpose

Nasal Decongestant

Antihistamine

Uses

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

- nasal congestion
- reduces swelling of the nasal passages
- runny nose
- sneezing
- itching of the nose or throat
- itchy, watery eyes

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

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

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
- avoid alcoholic drinks
- alcohol, sedatives, and tranquilizers may increase the drowsiness effect
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occurs
- symptoms do not improve within 7 days or 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 overdose, get medical help or contact a Poison Control Center right away.

Directions

- Do not exceed recommended dosage.
- Use enclosed dosage cup or tablespoon (TBSP).

Adults and children 12 years of age and over:	15 mL (1 TBSP) every 4 hours, not to exceed 90 mL (6 TBSP) in a 24 hour period.
Children 6 to under 12 years of age:	7.5 mL (1/2 TBSP) every 4 hours, not to exceed 45 mL (3 TBSP) in a 24 hour period.
Children under 6 years of age:	Consult a doctor.

Other information

- Each 15 mL (TBSP) contains: Sodium 6 mg.
- Store at 59-86°F (15-30°C).

Inactive ingredients

citric acid anhydrous, cotton candy flavor, FD&C Red #40, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol, sucralose.

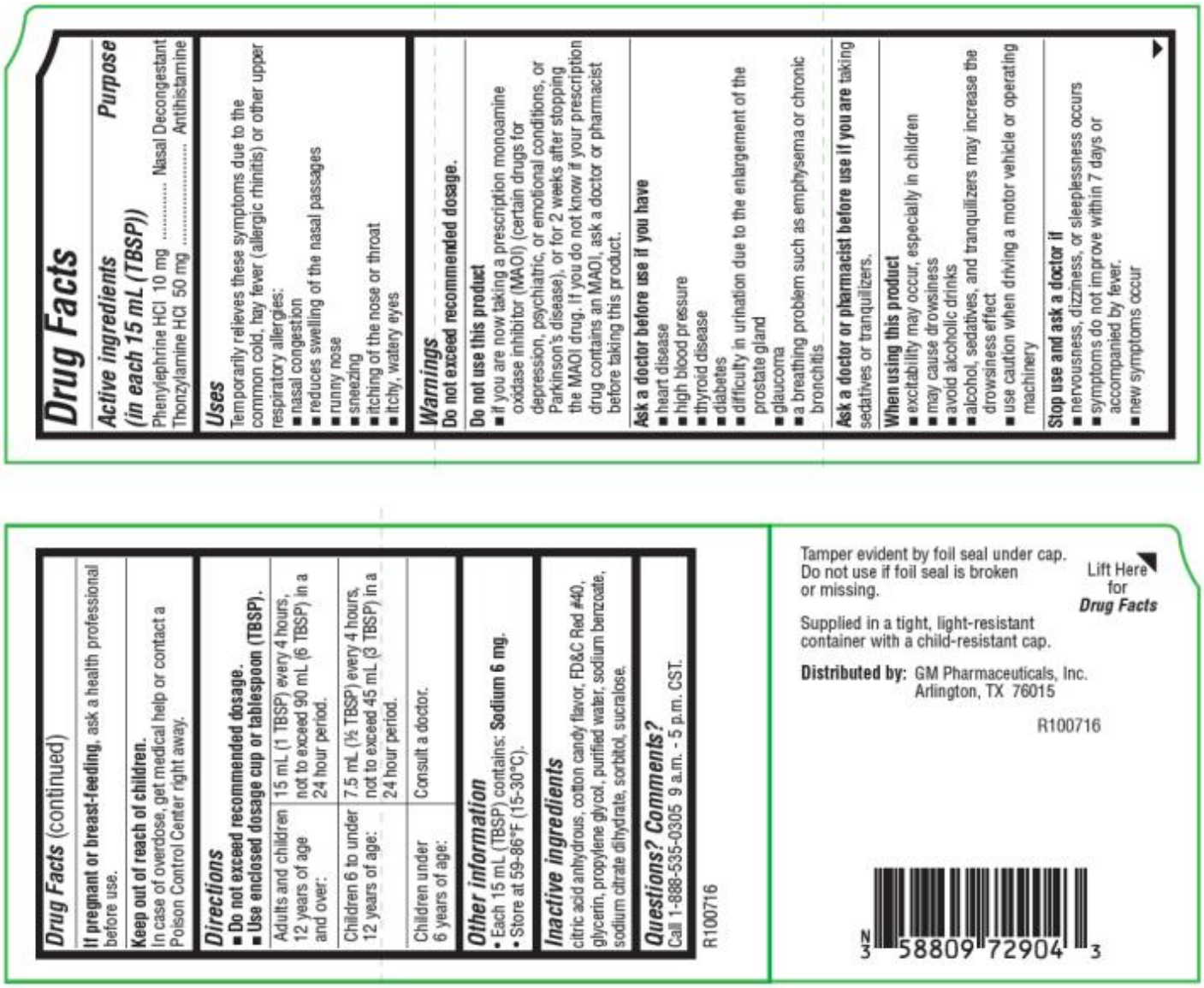
Questions? Comments?

Call 1-888-535-0305 9 a.m. - 5 p.m. CST.

R100716

PRINCIPAL DISPLAY PANEL

NDC 58809-729-04
NasOpenPE
Cotton Candy Flavor
4 fl.oz. (118 mL)



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Drug Facts (continued)

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Lift Here for *Drug Facts*

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Arlington, TX 76015

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NASOPEN PE

phenylephrine hydrochloride, thonzylamine hydrochloride liquid

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:58809-729
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg in 15 mL
THONZYLAMINE HYDROCHLORIDE (UNII: 6K9YKD48Y4) (THONZYLAMINE - UNII:R79646H5Z8)	THONZYLAMINE HYDROCHLORIDE	50 mg in 15 mL

Inactive Ingredients	
Ingredient Name	**Strength**

GLYCERIN (UNII: PDC6A3C0OX)	
MALTITOL (UNII: D65DG142WK)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0KO0R)	
SACCHARIN SODIUM (UNII: SB8ZUX40TY)	
SORBITOL (UNII: 506T60A25R)	
SUCRALOSE (UNII: 96K6UQ3ZD4)	

Product Characteristics

Color		**Score**	
Shape		**Size**	
Flavor	COTTON CANDY	**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58809-729-04	118 mL in 1 BOTTLE; Type 0: Not a Combination Product	10/03/2012	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	10/03/2012	

Labeler - GM Pharmaceuticals, INC (793000860)

Revised: 12/2017 GM Pharmaceuticals, INC