# NASOPEN PE- phenylephrine hydrochloride, thonzylamine hydrochloride liquid GM Pharmaceuticals, INC

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#### Nasopen PE

Nasopen PE

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 HCI 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                     | 15 mL (1 TBSP) every 4 hours,                                                      |  |  |
|-----------------------------------------|------------------------------------------------------------------------------------|--|--|
| 12 years of age                         | not to exceed 90 mL (6 TBSP) in a                                                  |  |  |
| and over:                               | 24 hour period.                                                                    |  |  |
| Children 6 to under<br>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                          | Consult a doctor                                                                   |  |  |

#### Other information

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

### **Inactive ingredients**

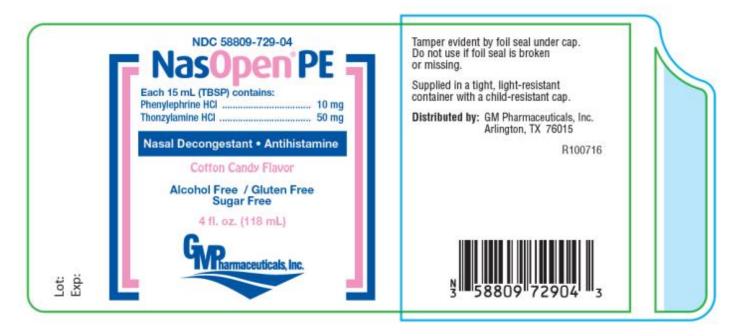
citric acid anhydrous, cotton candy flavor, FD&C Red #40, glycerin, propylene glycol, purified water, sodium benzoate, sodium citrate dihydrate, sorbitol, sucralose.

#### **Questions? Comments?**

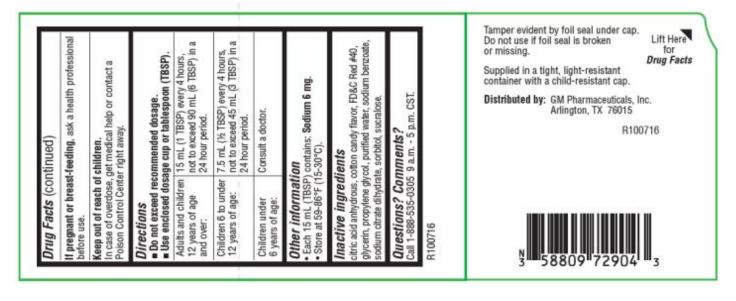
Call 1-888-535-0305 9 a.m. - 5 p.m. CST. R100716

#### PRINCIPAL DISPLAY PANEL

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



| Active ingredients (in each 15 mL (TBSP)) Phenylaphrine HCl 10 mg                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              | Drug Facts                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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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                                                                   | <b>Basis of Strength</b>       | Strength          |  |  |
| PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII: 1WS297W6MV) | PHENYLEPHRINE<br>HYDROCHLORIDE | 10 mg<br>in 15 mL |  |  |
| THONZYLAMINE HYDROCHLORIDE (UNII: 6K9YKD48Y4) (THONZYLAMINE - UNII:R79646H5Z8)    | THONZYLAMINE<br>HYDROCHLORIDE  | 50 mg<br>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                |              |              |  |

| l | Packaging |                      |                                                       |                         |                       |
|---|-----------|----------------------|-------------------------------------------------------|-------------------------|-----------------------|
|   | #         | Item Code            | Package Description                                   | Marketing Start<br>Date | Marketing End<br>Date |
|   | 1         | NDC:58809-729-<br>04 | 118 mL in 1 BOTTLE; Type 0: Not a Combination Product | 10/03/2012              | 11/30/2024            |

| Marketing Information |                                             |                         |                       |
|-----------------------|---------------------------------------------|-------------------------|-----------------------|
| Marketing<br>Category | Application Number or Monograph<br>Citation | Marketing Start<br>Date | Marketing End<br>Date |
| OTC Monograph Drug    | M012                                        | 10/03/2012              | 11/30/2024            |
|                       |                                             |                         |                       |

# **Labeler -** GM Pharmaceuticals, INC (793000860)

Revised: 11/2023 GM Pharmaceuticals, INC