PHYSICIANSCARE SINUS NON-DROWSY- phenylephrine hcl tablet, film coated Acme United Corporation

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.

PhysiciansCare Sinus

Drug Facts

Active ingredient (in each tablet)

Phenylephrine HCl 10mg

Purpose

Nasal Decongestant

Uses

Temporarily relieves

- nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- sinus congestion and pressure

Promotes nasal and/or sinus drainage.

Warnings

Do not use

■ 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
- trouble urinating due to an enlarged prostate gland

When using this product

■ do not exceed recommended dosage

Stop use and ask a doctor if

■ you get nervous, dizzy or sleepless

■ symptoms do not improve within 7 days or are accompanied by fever

If pregnant or breast-feeding, ask a health professional before use.

Keep out of the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

■ do not use more than directed

Adults and children: (12 years and older) Take 1 tablet every 4 hours. Do not take more than 6 doses in 24 hours.

Children under 12 years: Do not give to children under 12 years of age

Other information

- read all product information before using
- store at room temperature 59°-86° F (15°-30° C)
- tamper evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

croscarmellose sodium, FD&C red #40, FD&C yellow # 6, hypromellose, lactose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, propylene glycol, silicon dioxide, titanium dioxide

Questions or comments?

1-800-835-2263

Physicians Care Sinus Label

980087

Physicians Care®

Non-Drowsy Sinus

Decongestant Clears Sinus Pressure & Congestion

Pull To Open

Coated Tablets

Tamper-Evident Packets of 1 Tablet

Do not use if packet is open or torn.

Phenylephrine HCl 10mg

50 Tabletsts (50 Packets, 1 tablet each)



PHYSICIANSCARE SINUS NON-DROWSY

phenylephrine hcl tablet, film coated

Product Information

Product Type HUMAN OTC DRUG **Item Code (Source)** NDC:0924-0133

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Strength **Basis of Strength** PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE -**PHENYLEPHRINE**

UNII:1WS297W6MV)

HYDROCHLORIDE

10 mg

| Inactive Ingredients | | | |
|--|----------|--|--|
| Ingredient Name | Strength | | |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | | | |
| CROSCARMELLOSE SODIUM (UNII: M28OL1HH48) | | | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | | | |
| FD&C YELLOW NO. 6 (UNII: H77VEI93A8) | | | |
| HYPROMELLOSES (UNII: 3NXW29V3WO) | | | |
| LACTOSE (UNII: J2B2A4N98G) | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | |
| POLYETHYLENE GLYCOL 2000 (UNII: HAF0412YIT) | | | |

| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
|-------------------------------------|--|
| SILICON DIOXIDE (UNII: ETJ7Z6XBU4) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |

| Product Characteristics | | | | |
|-------------------------|---------------|--------------|----------|--|
| Color | red (red) | Score | no score | |
| Shape | ROUND (ROUND) | Size | 7mm | |
| Flavor | | Imprint Code | 272 | |
| Contains | | | | |

| P | Packaging | | | | | |
|---|----------------------|--|-------------------------|-----------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:0924-0133- 01 | 50 in 1 CARTON | 01/29/2012 | | | |
| 1 | NDC:0924-0133- 00 | 1 in 1 PACKET; Type 0: Not a Combination Product | | | | |
| 2 | NDC:0924-0133- 03 | 10 in 1 CARTON | 01/29/2012 | | | |
| 2 | NDC:0924-0133- 00 | 1 in 1 PACKET; 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 | 01/29/2012 | | |
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Labeler - Acme United Corporation (001180207)

Revised: 7/2022 Acme United Corporation