# SU PHEDRINE PE SINUS CONGESTION- phenylephrine hcl tablet, film coated Salado Sales, Inc.

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## **CVP 44-453 Sinus Congestion**

## Active ingredient (in each tablet)

Phenylephrine HCl 10 mg

## Purpose

Nasal decongestant

## Uses

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

## 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
- diabetes
- thyroid disease
- high blood pressure
- difficulty in urination due to enlargement of the prostate gland

## When using this product

## do not exceed recommended dosage.

## Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or occur with fever

## 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

- adults and children 12 years and over: take 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.
- children under 12 years: ask a doctor

## Other information

- TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- see end flap for expiration date and lot number

## Inactive ingredients

croscarmellose sodium, dextrose monohydrate, dibasic calcium phosphate dihydrate, FD&C red #40, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, silicon dioxide, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide

## **Questions or comments?**

1-800-426-9391

## **Principal Display Panel**

CVP® HEALTH

COMPARE TO SUDAFED PE® SINUS CONGESTION ACTIVE INGREDIENT\*

NON-DROWSY SU•PHEDRINE PE SINUS CONGESTION PHENYLEPHRINE HYDROCHLORIDE NASAL DECONGESTANT MAXIMUM STRENGTH

RELIEVES NASAL & SINUS CONGESTION CONTAINS NO PSEUDOEPHEDRINE

# **18 TABLETS**

10 mg EACH 1 PILL PER DOSE

TAMPER EVIDENT: DO NOT USE IF

## PACKAGE IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

\*This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark SUDAFED PE® SINUS CONGESTION. 50844 REV0820N45344

Distributed by Consumer Value Products, Inc. P.O. Box 6115, Temple, Texas 76502 CVPproducts.com



## SU PHEDRINE PE SINUS CONGESTION

phenylephrine hcl tablet, film coated

| Product Infor  |  |   |  |                      |                           |                               |                   |
|--|--|---|--|----------------------|---------------------------|-------------------------------|-------------------|
| Product Type   |  | HUMAN OTC DR  | UG <b>Item</b>   | Code (S              | Source)                   | NDC:572                       | 243-953           |
| Route of Admini  | istration  | ORAL  |  |                      |                           |                               |                   |
|  |  |   |  |                      |                           |                               |                   |
| Active Ingredi   | ient/Activ   | e Moiety  |  |                      |                           |                               |                   |
|  | Ing  | redient Name  |  |                      | Basis of S                | strength                      | Strengt           |
| PHENYLEPHRINE H<br>JNII:1WS297W6MV)  | TNSJ) (PHENYLEP  |   |  |                      | 10 mg                     |                               |                   |
| Inactive Ingre   | dients   |   |  |                      |                           |                               |                   |
|  |  | Ingredie  | nt Name  |                      |                           |                               | Strength          |
|  |  | UNII: M28OL1HH48)   |  |                      |                           |                               |                   |
| DEXTROSE MONO  |  |   |  |                      |                           |                               |                   |
|  |  | E DIHYDRATE (UNI  | ll: 07TSZ97GEP)  |                      |                           |                               |                   |
| FD&C RED NO. 40  | -  |   |  |                      |                           |                               |                   |
| LECITHIN, SOYBE  |  |   |  |                      |                           |                               |                   |
| MAGNESIUM STEA   |  |   |  |                      |                           |                               |                   |
| MALTODEXTRIN (L  | JNII: /CVR/L4  | IAZD)   |  |                      |                           |                               |                   |
| MICDOCDVSTALLU   |  |   | 6111)  |                      |                           |                               |                   |
|  |  |   | 61U)   |                      |                           |                               |                   |
| SILICON DIOXIDE  | (UNII: ETJ7Z6  | SXBU4)  |  | 790BS311             | )                         |                               |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL   | (UNII: ETJ7Z6<br>CELLULOSE   | SXBU4)<br>E <b>SODIUM, UNSPEC</b>   | CIFIED (UNII: K6   | 790BS311             | )                         |                               |                   |
| MICROCRYSTALLII<br>SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXIDI   | (UNII: ETJ7Z6<br>CELLULOSE<br>TE DIHYDRA   | 5XBU4)<br>E <b>Sodium, Unspec</b><br>Ate (Unii: B22547B <sup>.</sup>  | CIFIED (UNII: K6   | 790BS311             | )                         |                               |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA  | (UNII: ETJ7Z6<br>CELLULOSE<br>TE DIHYDRA   | 5XBU4)<br>E <b>Sodium, Unspec</b><br>Ate (Unii: B22547B <sup>.</sup>  | CIFIED (UNII: K6   | 790BS311             | )                         |                               |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA  | (UNII: ETJ7Z6<br>CELLULOSE<br>TE DIHYDRA   | 5XBU4)<br>E <b>Sodium, Unspec</b><br>Ate (Unii: B22547B <sup>.</sup>  | CIFIED (UNII: K6   | 79OBS 311            | )                         |                               |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXIDI  | (UNII: ETJ7ZE<br>CELLULOSE<br>TE DIHYDRA<br>E (UNII: 15FI)   | 5XBU4)<br>E <b>SODIUM, UNSPE(</b><br>ATE (UNII: B22547B<br>K9V2JP)  | CIFIED (UNII: K6   | 79OBS 311            | )                         |                               |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXIDI<br><b>Product Chara</b>  | (UNII: ETJ7Z&<br>CELLULOSE<br>TE DIHYDR/<br>E (UNII: 15FI)<br>Acteristic   | 5XBU4)<br>E <b>SODIUM, UNSPE(</b><br>ATE (UNII: B22547B<br>K9V2JP)  | CIFIED (UNII: K6   | 79OBS 311            | )                         | no score                      |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA  | (UNII: ETJ7Z&<br>CELLULOSE<br>TE DIHYDR/<br>E (UNII: 15FI)<br>Acteristic   | SXBU4)<br>SODIUM, UNSPEC<br>ATE (UNII: B22547B<br>(9V2JP)<br>SS<br>ed   | C <b>IFIED</b> (UNII: K6 <sup>-</sup><br>95K)  | 79OBS 311            | )                         | no score<br>7mm               |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXIDI<br><b>Product Chara</b><br>Color<br>Shape  | (UNII: ETJ7Z&<br>CELLULOSE<br>TE DIHYDR/<br>E (UNII: 15FI)<br>Acteristic   | SXBU4)<br>SODIUM, UNSPEC<br>ATE (UNII: B22547B<br>(9V2JP)<br>S<br>ed<br>ROUND   | CIFIED (UNII: K6<br>95K)<br>Score  | 79OBS 311            | )                         |                               |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXIDI<br><b>Product Chara</b><br>Color   | (UNII: ETJ7Z&<br>CELLULOSE<br>TE DIHYDR/<br>E (UNII: 15FI)<br>Acteristic   | SXBU4)<br>SODIUM, UNSPEC<br>ATE (UNII: B22547B<br>(9V2JP)<br>S<br>ed<br>ROUND   | CIFIED (UNII: K6<br>95K)<br>Score<br>Size  | 79OBS 311            | )                         | 7mm                           |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXIDI<br><b>Product Chara</b><br>Color<br>Shape<br>Flavor  | (UNII: ETJ7Z&<br>CELLULOSE<br>TE DIHYDR/<br>E (UNII: 15FI)<br>Acteristic   | SXBU4)<br>SODIUM, UNSPEC<br>ATE (UNII: B22547B<br>(9V2JP)<br>S<br>ed<br>ROUND   | CIFIED (UNII: K6<br>95K)<br>Score<br>Size  | 79OBS 311            | )                         | 7mm                           |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXIDI<br><b>Product Chara</b><br>Color<br>Shape<br>Flavor<br>Contains  | (UNII: ETJ7Z&<br>CELLULOSE<br>TE DIHYDR/<br>E (UNII: 15FI)<br>Acteristic   | SXBU4)<br>SODIUM, UNSPEC<br>ATE (UNII: B22547B<br>(9V2JP)<br>S<br>ed<br>ROUND   | CIFIED (UNII: K6<br>95K)<br>Score<br>Size  |                      |                           | 7mm<br>44;453                 |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXIDI<br>Product Chara<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging<br># Item Code                           | (UNII: ETJ7Z &<br>CELLULOSE<br>TE DIHYDR/<br>E (UNII: 15FI)<br>ACTERISTIC<br>R<br>R  | SXBU4)<br>SODIUM, UNSPEC<br>ATE (UNII: B22547B<br>(9V2JP)<br>S<br>ed<br>ROUND   | CIFIED (UNII: Кб <sup>а</sup><br>95К)<br>Score<br>Size<br>Imprint Code                   |                      | )<br>keting Start<br>Date | 7mm<br>44;453<br><b>Marke</b> | eting End<br>Date |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXID<br>Product Chara<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging<br># Item Code                            | (UNII: ETJ7Z &<br>CELLULOSE<br>TE DIHYDR/<br>E (UNII: 15FI)<br>ACTERISTIC<br>R<br>R  | SXBU4)<br>SODIUM, UNSPEC<br>ATE (UNII: B22547B<br>(9V2JP)<br>S<br>ed<br>ROUND<br>Package Descri                               | CIFIED (UNII: Кб <sup>а</sup><br>95К)<br>Score<br>Size<br>Imprint Code                   |                      | keting Start<br>Date      | 7mm<br>44;453<br><b>Marke</b> |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXIDI<br>Product Chara<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging<br># Item Code<br>1 NDC:57243-<br>953-44 | (UNII: ETJ7Z &<br>CELLULOSE<br>TE DIHYDRA<br>E (UNII: 15FI)<br>ACTERISTIC<br>r<br>R<br>1 in 1 CARTO                                | SXBU4)<br>SODIUM, UNSPEC<br>ATE (UNII: B22547B<br>(9V2JP)<br>S<br>ed<br>ROUND<br>Package Descri                               | CIFIED (UNII: K6<br>95K)<br>Score<br>Size<br>Imprint Code                                | <b>Mar</b><br>01/15/ | keting Start<br>Date      | 7mm<br>44;453<br><b>Marke</b> |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXIDI<br>Product Chara<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging<br># Item Code<br>1 NDC:57243-<br>953-44 | (UNII: ETJ7Z 6<br>CELLULOSE<br>TE DIHYDRA<br>E (UNII: 15FI)<br>ACTERISTIC<br>r<br>R<br>1 in 1 CART(<br>18 in 1 BLIS                | SXBU4)<br>SODIUM, UNSPEC<br>ATE (UNII: B22547B<br>(9V2JP)<br>S<br>ed<br>ROUND<br>Package Descri<br>DN                         | CIFIED (UNII: K6<br>95K)<br>Score<br>Size<br>Imprint Code                                | <b>Mar</b><br>01/15/ | keting Start<br>Date      | 7mm<br>44;453<br><b>Marke</b> |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXIDI<br>Product Chara<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging<br># Item Code<br>1 NDC:57243-<br>953-44 | (UNII: ETJ7Z 6<br>CELLULOSE<br>TE DIHYDRA<br>E (UNII: 15FI)<br>ACTERISTIC<br>ACTERISTIC<br>I in 1 CART(<br>18 in 1 BLIS<br>Product | SXBU4)<br>SODIUM, UNSPEC<br>ATE (UNII: B22547B<br>(9V2JP)<br>SS<br>ed<br>ROUND<br>Package Descri<br>DN<br>TER PACK; Type 0: 1 | CIFIED (UNII: K6<br>95K)<br>Score<br>Size<br>Imprint Code                                | <b>Mar</b><br>01/15/ | keting Start<br>Date      | 7mm<br>44;453<br><b>Marke</b> |                   |
| SILICON DIOXIDE<br>CARBOXYMETHYL<br>TRISODIUM CITRA<br>TITANIUM DIOXIDI<br>Product Chara<br>Color<br>Shape<br>Flavor<br>Contains<br>Packaging<br># Item Code<br>1 NDC:57243-           | (UNII: ETJ7Z 6<br>CELLULOSE<br>TE DIHYDRA<br>E (UNII: 15FI)<br>ACTERISTIC<br>I in 1 CARTO<br>18 in 1 BLIS<br>Product               | SXBU4)<br>SODIUM, UNSPEC<br>ATE (UNII: B22547B<br>(9V2JP)<br>SS<br>ed<br>ROUND<br>Package Descri<br>DN<br>TER PACK; Type 0: 1 | CIFIED (UNII: K6<br>95K)<br>Score<br>Size<br>Imprint Code<br>iption<br>Not a Combination | Mar<br>01/15/<br>n   | keting Start<br>Date      | 7mm<br>44;453                 |                   |

## Labeler - Salado Sales, Inc. (009830555)

| Address<br>Add | ID/FEI<br>832867837<br>dress | ID/FEI    | Business Operations<br>57243-953) , pack(57243-953)<br>Business Operations |  |  |  |  |  |  |
|----------------|------------------------------|-----------|--|--|--|--|--|--|--|
| Ade            | dress                        | ID/FEI    | ·  |  |  |  |  |  |  |
| Ado            |                              |           | Business Operations  |  |  |  |  |  |  |
| Ade            |                              |           | <b>Business Operations</b>   |  |  |  |  |  |  |
| Ad             |                              |           | <b>Business Operations</b>   |  |  |  |  |  |  |
|                | 8                            |           |  |  |  |  |  |  |  |
|                | U                            | 32867894  | manufacture(57243-953)   |  |  |  |  |  |  |
|                |                              |           |  |  |  |  |  |  |  |
|                |                              |           |  |  |  |  |  |  |  |
| Ad             | dress                        | ID/FEI    | <b>Business Operations</b>   |  |  |  |  |  |  |
|                | 8                            | 868734088 | manufacture(57243-953)   |  |  |  |  |  |  |
|                |                              |           |  |  |  |  |  |  |  |
| Establishment  |                              |           |  |  |  |  |  |  |  |
| Ad             | dress                        | ID/FEI    | <b>Business Operations</b>   |  |  |  |  |  |  |
|                | 1                            | 17025878  | manufacture(57243-953)   |  |  |  |  |  |  |
|                |                              | Address   | 868734088  |  |  |  |  |  |  |

Revised: 1/2025

Salado Sales, Inc.