**SUDO-TAB PE- phenylephrine hydrochloride tablet**
**HART 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.*

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**SUDO-TAB PE**

Active Ingredient (in each tablet): Phenylephrine HCl 5mg

Purpose: Nasal Decongestant

Uses: Temporarily relieves nasal congestion and sinus pressure due to
- the common cold
- hay fever
- upper respiratory allergies

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), for 2 weeks after stopping the MAOI drug, or if you do not know if your prescription drug contains and MAOI.

Ask a doctor before use if you have
- heart disease
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland

Stop use and ask a doctor if
- you get nervous, dizzy or sleepless
- symptoms do not improve within 7 days
- symptoms are accompanied by a fever

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

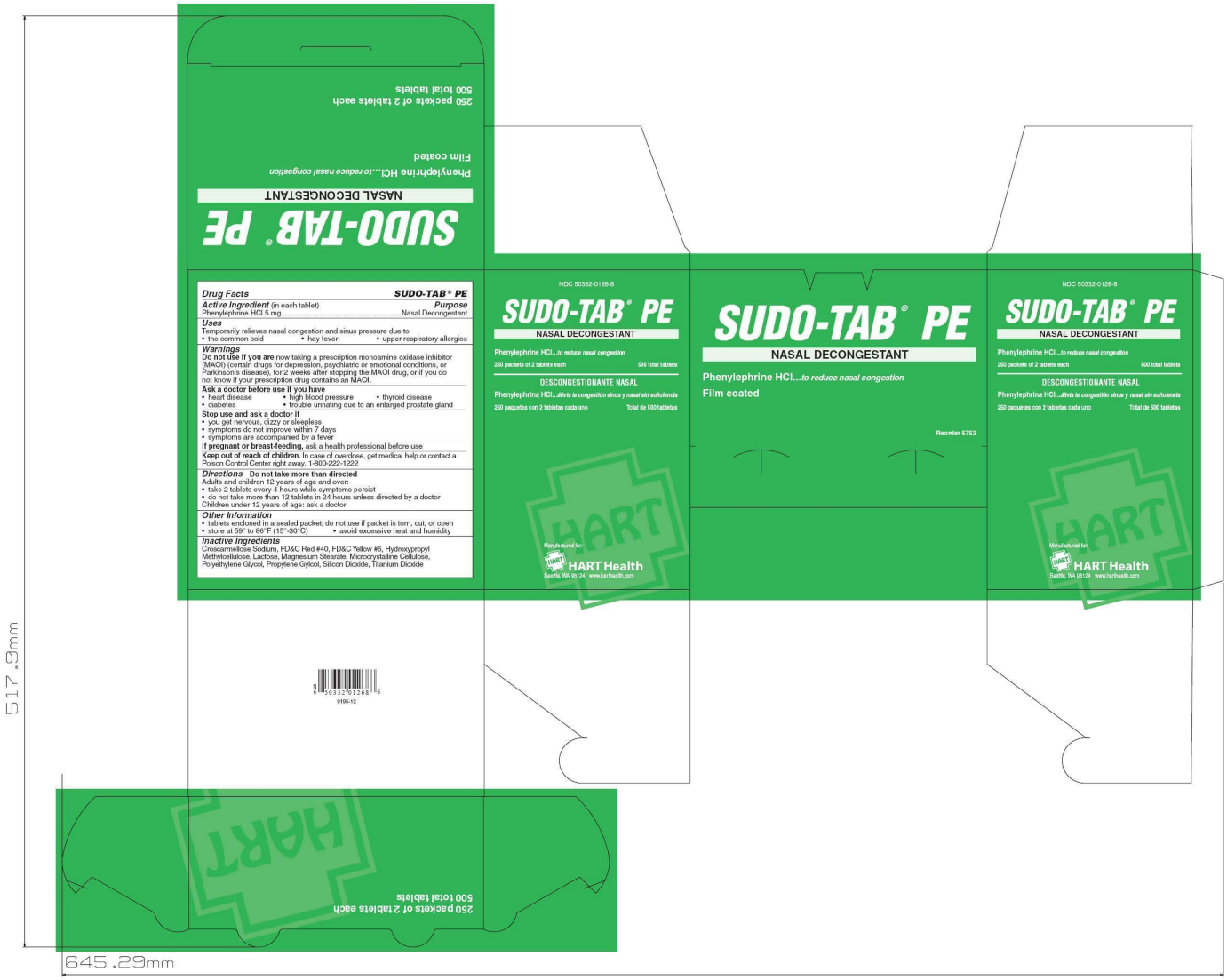
Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away. 1-800-222-1222

Directions: do not take more than directed

Adults and children 12 years of age and over:
- take 2 tablets every 4 hours while symptoms persist
- do not take more than 12 tablets in 24 hours unless directed by a doctor

Children under 12 years of age: ask a doctor

Inactive Ingredients: Croscarmellose Sodium, FD&C Red #40, FD&C Yellow #6, Hydroxypropyl Methylcellulose, Lactose, Magnesium Stearate, Microcrystalline Cellulose, Polyethylene Glycol, Propylene Glycol, Silicon Dioxide, Titanium Dioxide




## SUDO-TAB PE

phenylephrine hcl tablet

| Product Information | | | |
|---|---|---|---|
| **Product Type** | HUMAN OTC DRUG LABEL | **Item Code (Source)** | NDC:50332-0126 |
| **Route of Administration** | ORAL | **DEA Schedule** | |

| Active Ingredient/Active Moiety | | |
|---|---|---|
| **Ingredient Name** | **Basis of Strength** | **Strength** |
| **PHENYLEPHRINE HYDROCHLORIDE** (PHENYLEPHRINE) | PHENYLEPHRINE | 5 mg |

## Inactive Ingredients

| Ingredient Name | Strength |
|---|---|
| CROSCARMELLOSE SODIUM | |
| FD&C RED NO. 40 | |
| FD&C YELLOW NO. 6 | |
| LACTOSE | |
| MAGNESIUM STEARATE | |
| CELLULOSE, MICROCRYSTALLINE | |
| PROPYLENE GLYCOL | |
| SILICON DIOXIDE | |
| TITANIUM DIOXIDE | |

## Product Characteristics

| | | | |
|---|---|---|---|
| **Color** | red | **Score** | no score |
| **Shape** | ROUND | **Size** | 8mm |
| **Flavor** | | **Imprint Code** | 271 |
| **Contains** | | | |

## Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|---|---|---|---|
| 1 | NDC:50332-0126-4 | 50 in 1 BOX, UNIT-DOSE | | |
| 1 | | 2 in 1 PACKET | | |
| 2 | NDC:50332-0126-7 | 125 in 1 BOX, UNIT-DOSE | | |
| 2 | | 2 in 1 PACKET | | |
| 3 | NDC:50332-0126-8 | 250 in 1 BOX, UNIT-DOSE | | |
| 3 | | 2 in 1 PACKET | | |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|---|---|---|---|
| OTC monograph final | part341 | 10/03/2005 | |

## Labeler - HART Health (069560969)

Revised: 11/2012 HART Health