# SUNMARK NASAL DECONGESTANT PE MAXIMUM STRENGTH- phenylephrine hydrochloride tablet, film coated Strategic Sourcing Services LLC

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.

-----

# McKesson Nasal Decongestant PE Drug Facts

# Active ingredient (in each tablet)

Phenylephrine HCI 10 mg

#### **Purpose**

Nasal decongestant

#### Uses

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

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

adults and children 12 years and over	<ul> <li>take 1 tablet every 4 hours</li> <li>do not take more than 6 tablets in 24 hours</li> </ul>
children under 12 years	do not use this product in children under 12 years of age

#### Other information

- store at 20-25°C (68-77°F)
- do not use if blister unit is broken or torn

# **Inactive ingredients**

anhydrous dibasic calcium phosphate, carnauba wax, FD&C red no. 40 aluminum lake, lecithin, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, silicon dioxide, talc, titanium dioxide

# Questions or comments?

1-800-719-9260

# **Principal Display Panel**

COMPARE TO SUDAFED PE® CONGESTION

**ACTIVE INGREDIENT** 

nasal decongestant PE

Maximum Strength

Phenylephrine HCl Tablets, 10 mg

Nasal & sinus congestion - Sinus pressure

36 doses - 1 pill/dose

**GLUTEN FREE** 

**NON-DROWSY** 

**Actual Size** 

36 TABLETS 10 mg EACH



Important: Rea d all product information before using. Keep this box for important information.

#### **Drug Facts**

09468 S1 C4

Active ingredient (in each tablet) Purpose 

■ temporarily relieves sinus congestion and pressure ■ temporarily relieves na sal congestion due to the common cold, hay fe ver or other upper respiratory all engies

Warnings

OPEN OTHER END

Do not use if you are now taking a prescription moncamine oxid as einhibitor (MAOI) (certain drugs for de pression, 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.

Aska doctor before use if you have

- heart dise ase ■ high blood pressure
- th yroid disease diabetes trouble urina ting due to an en larged prostate gland

When using this product do not exceed recommended dosage

Stop use and ask a doctorif

■ n ervou an ess, d izzin ess, or sleepl es an ess occur

■ symptomsdo not improve within 7 days or occur with a fe ver

If pregnant or breast-feeding, ask a health professional

Ke ep out of reach of children. In case o fo verdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

#### Drug Facts (continued)

#### Directions

adults and children ■ take 1 ta blet every 4 hours 12 years and over do not ta ke mor e than 6 tab lets in 24hours children under 12 years ask adoctor

#### Other Information

- store at 20-25°C (68-77°F)
- do not use if blister unit is broken or torn

Inactive ingredients anhydrous dibasic calcium phosphate, cama uba wax, FD&C red no. 40 aluminum lake, leci thin , magnesium stearate , microcrystall ine cel lulose, pol ye thylene g lycol, p olyvinyl al cohol , si lico n dioxi de, tal c, titanium dioxide

#### Questions or comments? 1-800-719-9260

\*This product is not manufactured or distributed by McNeil Consumer Heal thcare, distributor of Sudafe d PE® Congestion.

# **M**KESSON

Another Quality Product Distributed By McKes so 06565 State High way 161, Irving, TX 75039 Money Back Guarente e Please visit us at www.sunmark brandcom





# SUNMARK NASAL DECONGESTANT PE MAXIMUM STRENGTH

phenylephrine hydrochloride tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-700
Route of Administration	ORAL		

l	Active Ingredient/Active Moiety		
	Ingredient Name	Basis of Strength	Strength
	<b>PHENYLEPHRINE HYDRO CHLO RIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6 MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients		
Ingredient Name	Strength	
CARNAUBA WAX (UNII: R12CBM0 EIZ)		
ANHYDRO US DIBASIC CALCIUM PHO SPHATE (UNII: L11K75P92J)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)		
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)		
TALC (UNII: 7SEV7J4R1U)		
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		

Product Characteristics				
Color	RED	Score	no score	
Shape	ROUND	Size	8mm	
Flavor		Imprint Code	L7	
Contains				

P	Packaging				
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>	
1	NDC:49348-700- 48	1 in 1 CARTON	02/14/2005		
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:49348-700- 07	2 in 1 CARTON	02/14/2005		
2		18 in 1 BLISTER PACK; 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	02/14/2005	

# Labeler - Strategic Sourcing Services LLC (116956644)

Revised: 1/2021 Strategic Sourcing Services LLC