

FIRST AID DIRECT NASAL AND SINUS DECONGESTANT- phenylephrine hcl tablet

Cintas 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.

First Aid Direct Nasal and Sinus Decongestant

Active ingredient (in each tablet)

Phenylephrine HCl 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 dose

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 (1-800-222-1222) right away.

Directions

Adults and children 12 years and over:

- 1 tablet every 4 hours
- do not take more than 6 tablets in 24 hours

Children under 12 years: ask a doctor

Other information

- store at room temperature 20°-25°C (68°-77°F)
- do not use if packet is opened or torn

Inactive ingredients

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

Questions or comments?

Call 1-800-327-2704 M-F 8AM-5PM

Principal Display Panel - 25 CT Box

NASAL & SINUS DECONGESTANT

- Compare to active ingredients in SUDAFED PE® Sinus Congestion*
- Helps to temporarily relieve: sinus congestion and pressure, nasal congestion due to the common cold, hay fever or other upper respiratory allergies

25 Tablets • 1 Tablet per Packet

NASAL & SINUS DECONGESTANT

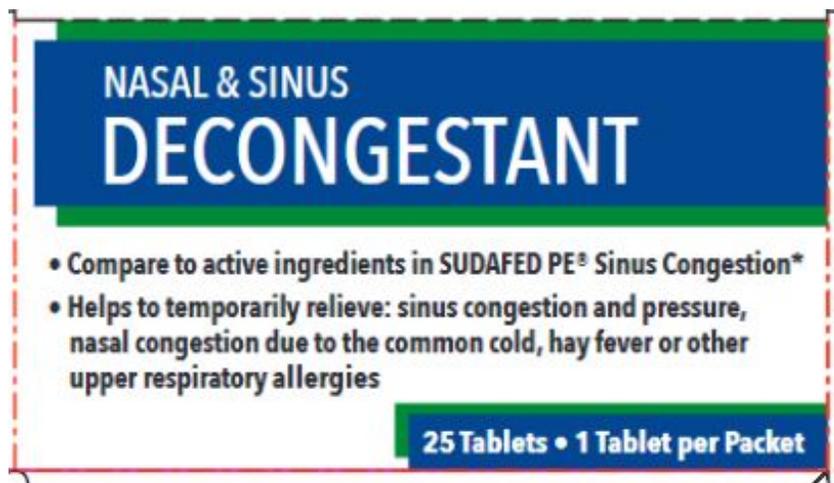
Active Ingredient:

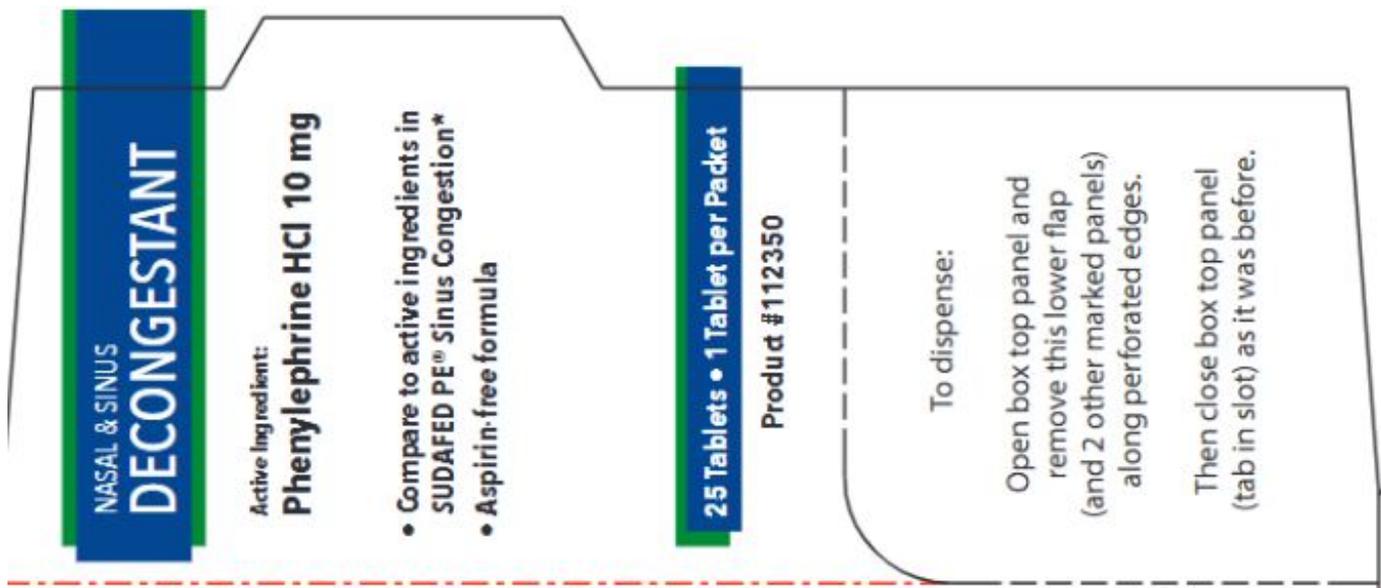
Phenylephrine HCl 10 mg

- Compare to active ingredients in SUDAFED PE® Sinus Congestion*
- Aspirin-free formula

25 Tablet • 1 Tablet per Packet

Product #112350





FIRST AID DIRECT NASAL AND SINUS DECONGESTANT

phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42961-125
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE	10 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	Score	no score
Shape	ROUND	Size	8mm

Flavor		Imprint Code	272
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42961-125-02	25 in 1 BOX	08/09/2023	
1	NDC:42961-125-01	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	08/09/2023	

Labeler - Cintas Corporation (056481716)

Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	manufacture(42961-125)

Revised: 8/2023

Cintas Corporation