NASAL DECONGESTANT- phenylephrine hcl tablet
Spirit Pharmaceuticals 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.

Maximum Strength Nasal Decongestant

Drug Facts

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

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

store between 20° to 25°C (68° to 77°F)

Inactive ingredients

carnauba wax*, colloidal silicon dioxide*, croscarmellose sodium*, D&C yellow#10 aluminum lake*, dicalcium phosphate*, FD&C Blue#1*, FD&C Red #40 , FD&C Yellow#6*, hypromellose, lactose*, magnesium stearate, microcrytalline cellulose, polyethylene glycol, sodium starch glycolate*, starch*, stearic acid*, talc*, titanium dioxide
*contains one or more of these ingredients

Questions or comments? 1-888-333-9792

PRINCIPAL DISPLAY PANEL

COMPARE TO ACTIVE INGREDIENT IN

SUDAFED® PE CONGESTION®†

MAXIMUM STRENGTH

Nasal Decongestant

· Phenylephrine HCl 10 mg - Nasal Decongestant

Relieves Nasal & Sinus Congestion,
Reduces Sinus Pressure, Non-Drowsy

Actual Size

PSEUDOEPHEDRINE FREE

†This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Sudafed PE® Congestion

NASAL DECONGESTANT

phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68210-1081
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
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 400 (UNII: B697894SGQ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red	**Score**	no score
Shape	CAPSULE	**Size**	8mm
Flavor		**Imprint Code**	272;S08;T234
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-1081-2	1 in 1 CARTON	03/16/2020	
1		24 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	03/16/2020	

Labeler - Spirit Pharmaceuticals LLC (179621011)

Revised: 4/2020 Spirit Pharmaceuticals LLC