

MAXIMUM STRENGTH NASAL DECONGESTANT- phenylephrine hydrochloride tablet, coated
Spirit Pharmaceuticals LLC

Maximum Strength Nasal Decongestant

Drug Facts

Active Ingredient (in each tablet)

Phenylephrine Hydrochloride 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 & children 12 years & over	• take 1 tablet every 4 hours
children under 12 years	• do not take more than 6 tablets in 24 hours
	ask a doctor

Other information

- store between 20-25°C (68-77°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, microcrystalline cellulose, polyethylene glycol, sodium starch glycolate*, starch*, stearic acid*, talc*, *contains one or more of these ingredients

Questions or comments?

1-888-333-9792

Distributed By:

Spirit Pharmaceuticals, LLC

Ronkonkoma, NY 11779

Made in India

Carton



MAXIMUM STRENGTH



Nasal Decongestant

Phenylephrine HCl 10 mg - Nasal Decongestant

72 tablets

Made in India
 Distributed By: Spirit Pharmaceuticals, LLC
 Ronkonkoma, NY 11779 DRG 02/23

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

Questions or comments? 1-888-333-9792

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

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phenylephrine hydrochloride tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68210-5011
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

CROSCARMELOSE SODIUM (UNII: M28OL1HH48)
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)
CALCIUM PHOSPHATE (UNII: 97Z1W3NDX)
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)
FD&C RED NO. 40 (UNII: WZB9127XOA)
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)
HYPROMELLOSES (UNII: 3NXW29V3WO)
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)
MAGNESIUM STEARATE (UNII: 70097M6I30)
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)
STARCH, POTATO (UNII: 8I089SAH3T)
STEARIC ACID (UNII: 4ELV7Z65AP)
TALC (UNII: 7SEV7J4R1U)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)

Product Characteristics

Color	red	Score	no score
Shape	ROUND (biconvex)	Size	7mm
Flavor		Imprint Code	S08
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68210-5011-7	3 in 1 CARTON	02/10/2023	
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 Drug	M012	02/10/2023	

Labeler - Spirit Pharmaceuticals LLC (179621011)