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 & children12 years & 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 20-25°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 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)	

CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
D&C YELLOW NO. 10 ALUMINUM LAKE (UNII: CQ3XH3DET6)	
CALCIUM PHOSPHATE (UNII: 97Z1WI3NDX)	
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: 3WQ0SDW1A)	
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)

Revised: 12/2023 Spirit Pharmaceuticals LLC