PHENYLEPHRINE- phenylephrine tablet
Rebel Distributors Corp

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.

Phenylephrine Drug Facts

Active ingredient

Phenylephrine hydrochloride 10 mg

Purpose

Nasal decongestant

Keep Out of Reach of Children

In case of overdose, get medical help or contact a Poison Control Center right away.

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 exidase 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 ° diabetes ° trouble urinating due to an enlarge prostate gland ° thyroid disease

When using this product, do not use more than directed.

Stop use and ask a doctor if:

° you get nervous, dizzy or sleepless

° symptoms do not improve within 7 days or are accompanied by fever

If pregnant or breast-feeding, ask a health professional before use.

Directions

° take every 4 hours

° do not take more than 6 doses in 24 hours

° adults and children 12 years of age and over: 1 tablet

° children under 12 years of age: ask a doctor

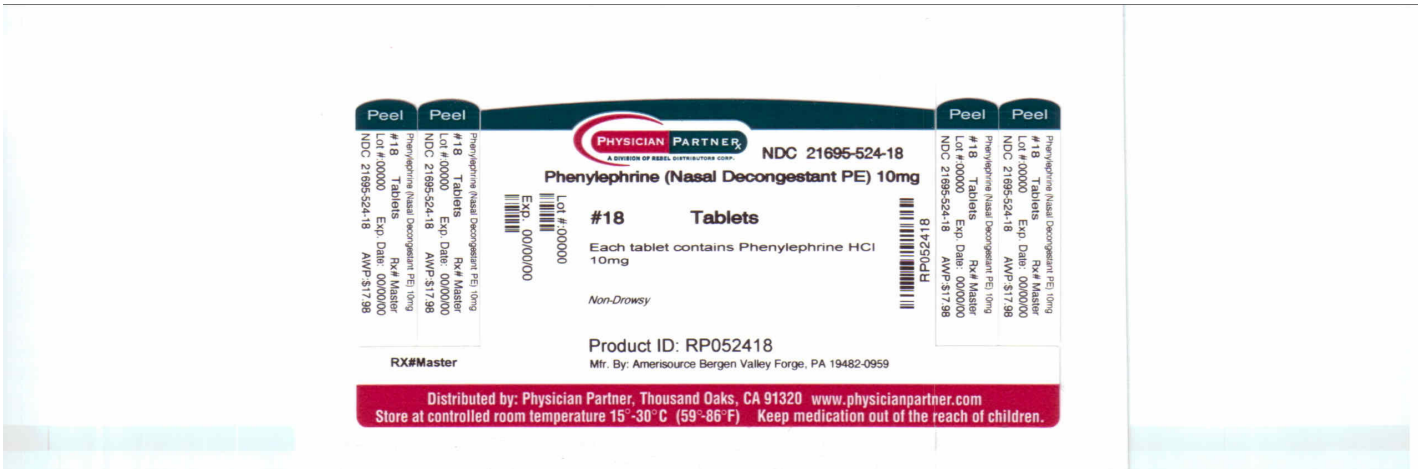
Other information

Store at room temperature (59°-86°F)

Inactive ingredients

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

Package/Label Principal Display Panel



PHENYLEPHRINE

phenylephrine tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:21695-524(NDC:24385-603)
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)	
ANHYDROUS DIBASIC CALCIUM PHOSPHATE (UNII: L11K75P92J)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	

POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYVINYL ALCOHOL (UNII: 532B59J990)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:21695-524-18	18 in 1 BLISTER PACK		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	02/24/2010	

Labeler - Rebel Distributors Corp (118802834)

Establishment

Name	Address	ID/FEI	Business Operations
Rebel Distributors Corp		118802834	RELABEL, REPACK

Revised: 2/2011 Rebel Distributors Corp