SUPHEDRINE PE - phenylephrine hcl tablet, film coated COSTCO WHOLESALE 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.

Drug Facts

Active ingredient

(in each tablet)

Phenylephrine HCl 10 mg

Purpose

Nasal decongestant

Uses

- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- temporarily relives sinus congestion and pressure

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
- diabetes
- thyroid disease
- trouble urinating due to an enlarged prostate gland

When using this product

do not exceed the recommended dosage

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- symptoms do not improve within 7 days or are accompanied by fever

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of the reach of children.

In case of overdose, get medical help or contact a Poison Control Center 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: do not use this product in children under 12 years of age

Other information

- store at controlled room temperature 15°-30°C (59° to 86°F)
- see end flap for expiration date and lot number

Inactive ingredients

croscarmellose sodium, dextrose monohydrate, dicalcium phosphate dihydrate, FD&C red #40, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, silica gel, sodium cardoxymethylcellulose, sodium citrate dihydrate, titanium dioxide

PRODUCT PACKAGING

The product packaging shown below represents a sample of that currently in use. Additional packaging may aslo be available.

KIRKLAND

SignatureTM

COMPARE TO

SUDAFED PETM

active ingredient*

NDC 63981-453-69

ITEM # 111266

NON-DROWSY

SUPHEDRINE PE

Phenylephrine Hydrochloride 10 mg

Nasal & Sinus Decongestant Formula

Temporary Relief of:

√ Nasal Congestion

√ Sinus Pressure & Congestion

√ Hay Fever Symptoms

Actual Size

1 Pill Per Dose

144

TABLETS

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING

50844 REV0810F45369

Manufactured by:

LNK INTERNATIONAL, INC.

60 Arkay Drive, Hauppauge, NY 11788 USA

For Costco Wholesale Corporation

P.O. Box 34535

Seattle, WA 98124-1535 USA

1-800-774-2678

www.cvs.com



SUPHEDRINE PE

phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:63981-453
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			
Croscarmellose Sodium (UNII: M28 OL 1HH48)				
Dextrose Monohydrate (UNII: LX22YL083G)				
Dibasic Calcium Phosphate Dihydrate (UNII: O7TSZ97GEP)				
Fd&c Red No. 40 (UNII: WZB9127XOA)				
Magnesium Stearate (UNII: 70097M6I30)				
Malto dextrin (UNII: 7CVR7L4A2D)				
Cellulose, Microcrystalline (UNII: OP1R32D61U)				
Silicon Dioxide (UNII: ETJ7Z6XBU4)				
Carboxymethylcellulose Sodium (UNII: K679OBS311)				
Trisodium Citrate Dihydrate (UNII: B22547B95K)				

Product Characteristics			
Color	RED	Score	no score
Shape	ROUND	Size	6 mm
Flavor		Imprint Code	44;453
Contains			

P	ackaging			
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63981-453-69	1 in 1 CARTON		
1		144 in 1 BLISTER PACK		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part341	12/06/2004	

Labeler - COSTCO WHOLESALE CORPORATION (103391843)

Registrant - L.N.K. International, Inc. (832867837)

Establishment			
Name	Address	ID/FEI	Business Operations
L.N.K. International, Inc		832867894	MANUFACTURE

Revised: 9/2010

COSTCO WHOLESALE CORPORATION