SUPHEDRINE PE- phenylephrine hcl tablet, film coated
GREAT LAKES WHOLESALE, MARKETING, & SALES, INC.

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.

Healthcare 44-453

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 relieves 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

- diabetes
- heart disease
- high blood pressure
- thyroid disease
- 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 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.

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: do not use this product in children under 12 years of age

Other information

- store at 25ºC (77ºF); excursions permitted between 15º-30ºC (59º-86ºF)
- 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 carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide

Questions or comments?

Call 1-800-426-9391

Principal Display Panel

HEALTHCARE™

NDC 64092-802-18

Suphedrine PE
Maximum Strength

Phenylephrine HCl 10 mg
Nasal Decongestant

Pseudoephedrine FREE

Relieves:
• Nasal & Sinus Congestion due to Colds & Allergies

Non-Drowsy

*Compare to the active ingredient in Sudafed PE®

18 TABLETS

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Sudafed PE®.
50844 REV1111F45344

Distributed by:
Great Lakes Wholesale
& Marketing L.L.C.
3729 Patterson Ave., S.E.
Grand Rapids, MI 49512
www.glwholesale.com

HEALTHCARE GUARANTEE
If you are not completely satisfied with this product, redardless of reason, return your unused portion to Great Lakes Wholesale for a full refund

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

Healthcare 44-453

SUPHEDRINE PE

phenylephrine hcl tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:64092-802
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: M28OL1HH48)	
DEXTROSE MONOHYDRATE (UNII: LX22YL083G)	
CALCIUM PHOSPHATE, DIBASIC, DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	RED	**Score**	no score
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	44;453
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:64092-802-18	1 in 1 CARTON	01/14/2005	
1		18 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	01/14/2005	

Labeler - GREAT LAKES WHOLESALE, MARKETING, & SALES, INC. (361925498)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(64092-802)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(64092-802)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(64092-802)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(64092-802)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(64092-802)

Revised: 9/2017 GREAT LAKES WHOLESALE, MARKETING, & SALES, INC.