

NASAL DECONGESTANT MAXIMUM STRENGTH- phenylephrine hcl tablet, coated
Chain Drug Consortium

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.

Premier Value 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

- heart disease
- diabetes
- thyroid disease
- high blood pressure
- difficulty in urination due to enlargement of the 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 (1-800-222-1222) 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: ask a doctor

Other information

- **TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN**
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-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 carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide

Questions or comments?

1-800-426-9391

Principal Display Panel

Premier Value®

***COMPARE TO THE ACTIVE INGREDIENT IN
SUDAFED PE® CONGESTION**

***Maximum Strength
Nasal Decongestant PE***

Phenylephrine HCl 10 mg
NASAL DECONGESTANT

Relief of:

- Sinus Pressure
- Congestion

Non-drowsy

18 Tablets

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

*This product is not manufactured
or distributed by McNeil Consumer
Healthcare, owner of the registered
trademark Sudafed PE® Congestion.
50844 ORG071545344

Distributed By:
Pharmacy Value Alliance, LLC
407 East Lancaster Avenue,
Wayne, PA 19087
www.emersongroup.com

If for any reason you are not satisfied with this product, please return it to the store where purchased for a full refund.

Maximum Strength
Nasal Decongestant PE
 Phenylephrine HCl 10 mg
NASAL DECONGESTANT 18 Tablets

PREMIER VALUE

OMI

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PREMIER VALUE

*COMPARE TO THE ACTIVE INGREDIENT IN SUDAFED PE® CONGESTION

Maximum Strength
Nasal Decongestant PE
 Phenylephrine HCl 10 mg
NASAL DECONGESTANT

Relief of:

- Sinus Pressure
- Congestion

Non-drowsy

18 Tablets

PREMIER VALUE

Maximum Strength
Nasal Decongestant PE
 Phenylephrine HCl 10 mg
NASAL DECONGESTANT

18 Tablets

B-1590-453-44
ORG071545344

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Drug Facts (continued)

Drug Facts (in each tablet) Phenylephrine HCl 10 mg 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 heart disease, high blood pressure, difficulty in urination due to enlargement of the prostate gland

When using this product do not exceed recommended dose.
Stop use and ask a doctor if symptoms do not improve within 7 days or occur with fever

Questions or comments? 1-800-426-9391

Drug Facts

Directions
adults and children 12 years and over: take 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.
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store at 25°C (77°F); excursions permitted between 15°-30°C (59°-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, maledextrin, microcrystalline cellulose, silica gel, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Premier Value 44-453

NASAL DECONGESTANT MAXIMUM STRENGTH

phenylephrine hcl tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68016-757
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)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
CARBOXYMETHYLCELLULOSE SODIUM (UNII: K679OBS311)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
TRISODIUM CITRATE DIHYDRATE (UNII: B22547B95K)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

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:68016-757-24	1 in 1 CARTON	01/14/2005	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:68016-757-15	2 in 1 CARTON	01/14/2005	
2		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 - Chain Drug Consortium (101668460)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(68016-757)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(68016-757)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(68016-757)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(68016-757)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(68016-757)