

**NASAL DECONGESTANT PE NON-DROWSY MAXIMUM STRENGTH-  
phenylephrine hcl tablet, film coated  
CHAIN DRUG MARKETING ASSOCIATION INC**

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**Quality Choice 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 dosage.**

**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: 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°C-30°C (59°F-86°F)
- see end flap for expiration date and lot number

### ***Inactive ingredients***

croscarmellose sodium, dextrose monohydrate, dibasic calcium phosphate dihydrate, FD&C red #40, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, silicon dioxide, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide

### ***Questions or comments?***

**1-800-426-9391**

### **Principal Display Panel**

**QC®  
QUALITY  
CHOICE**

NDC 63868-144-37

**\*Compare to the  
Active Ingredient in  
SUDAFED PE®  
SINUS CONGESTION**

**Non-Drowsy | Maximum Strength  
Nasal Decongestant PE  
Phenylephrine HCl 10 mg | Nasal Decongestant**

Sinus Pressure & Congestion Relief  
Does Not Include Pseudoephedrine

**36** Tablets

actual size

**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 Johnson & Johnson Corporation, owner of the  
registered trademark SUDAFED PE®  
SINUS CONGESTION.

50844 REV0820C45307

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43157 W 9 Mile Rd

Novi, MI 48375

[www.qualitychoice.com](http://www.qualitychoice.com)

Questions: 800-935-2362



NDC 63868-144-19

Non-Drowsy | Maximum Strength

# Nasal Decongestant PE

Phenylephrine HCl 10 mg | Nasal Decongestant



Phenylephrine HCl 10 mg | Nasal Decongestant  
Non-Drowsy | Maximum Strength  
**Nasal Decongestant PE**

NDC 63868-144-19



\*Compare to the  
Active Ingredient in  
**SUDAFED PE®**  
SINUS CONGESTION

Non-Drowsy | Maximum Strength

# Nasal Decongestant PE

Phenylephrine HCl 10 mg | Nasal Decongestant

Sinus Pressure & Congestion Relief  
Does Not Include Pseudoephedrine

actual size



18 Tablets

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

No Print / No Varnish  
Lot no. & Exp. date



\*This product is not manufactured or distributed  
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registered trademark SUDAFED PE®  
SINUS CONGESTION.  
50844 REV0820C45344



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43157 W 9 Mile Rd  
Novi, MI 48375  
www.qualitychoice.com  
Questions: 800-935-2362

B-0220-453-44  
REV0820C45344

<b>Drug Facts</b>	
<b>Active ingredient (in each tablet)</b> Phenylephrine HCl 10 mg	<b>Purpose</b> Nasal decongestant
<b>Uses</b> temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies	
<b>Warnings</b> 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 dosage.	
<b>Stop use and ask a doctor if</b> ■ symptoms do not improve within 7 days or occur with fever ■ nervousness, dizziness, or sleeplessness occur	
<b>Other information</b> ■ 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	
<b>Directions</b> 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	
<b>Drug Facts (continued)</b> 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.	
<b>Inactive ingredients</b> croscarmellose sodium, dextrose monohydrate, dibasic calcium phosphate dihydrate, FD&C red #40, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, silicon dioxide, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide	
<b>Questions or comments?</b> 1-800-426-9391	

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Quality Choice 44-453

## NASAL DECONGESTANT PE NON-DROWSY MAXIMUM STRENGTH

phenylephrine hcl tablet, film coated

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63868-144
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>PHENYLEPHRINE HYDROCHLORIDE</b> (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>DEXTROSE MONOHYDRATE</b> (UNII: LX22YL083G)	
<b>DIBASIC CALCIUM PHOSPHATE DIHYDRATE</b> (UNII: O7TSZ97GEP)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>LECITHIN, SOYBEAN</b> (UNII: 1DI56QDM62)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED</b> (UNII: K679OBS311)	
<b>TRISODIUM CITRATE DIHYDRATE</b> (UNII: B22547B95K)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

## Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	7mm
<b>Flavor</b>		<b>Imprint Code</b>	44;453
<b>Contains</b>			

## Packaging

<b>#</b>	<b>Item Code</b>	<b>Package Description</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:63868-144-19	1 in 1 CARTON	01/14/2005	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:63868-144-37	2 in 1 CARTON	01/14/2005	
2		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:63868-144-74	4 in 1 CARTON	01/14/2005	03/23/2022
3		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 Drug	M012	01/14/2005	

**Labeler** - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(63868-144) , pack(63868-144)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(63868-144)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(63868-144)

## Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(63868-144)

Revised: 1/2024

CHAIN DRUG MARKETING ASSOCIATION INC