## SINUS CONGESTION PE- phenylephrine hcl tablet, film coated L.N.K. International, Inc.

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#### Sound Body 44-453-Sinus Congestion-Delisted

#### 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°-30°C (59°-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

SOUND**BODY**™

\*Compare to the active ingredient in SUDAFED PE® SINUS CONGESTION

NDC 50844-443-07

MAXIMUM STRENGTH

Sinus Congestion PE

#### Phenylephrine HCI 10 mg, Nasal Decongestant

Relieves Sinus Pressure and Congestion

Non Drowsy

**Actual Size** 

**36 TABLETS** 

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

<sup>\*</sup>This product is not manufactured or distributed by Johnson &

Johnson Corporation, owner of the registered trademark SUDAFED PE® SINUS CONGESTION. 50844 ORG082045307

Manufactured for Big Lots Stores, Inc. by **LNK INTERNATIONAL, INC.** 60 Arkay Drive, Hauppauge, NY 11788 USA V#733000 ITEM#022745307BLBX



#### **MAXIMUM STRENGTH**

## Sinus Congestion PE

Phenylephrine HCl 10 mg, Nasal Decongestant



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NDC 50844-443-07

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B-0227-453-07-RR 0RG082045307

ANY SIGNS OF TAMPERING UNIT IS TORN, BROKEN OR SHOWS TAMPER EVIDENT: DO NOT USE IF Package is opened or if blister by **LNK INTERNATIONAL, INC.** O Akay Drive, Hauppauge, NY 11788 USA V#733000 ITEM#022745307BLBX Manufactured for Big Lots Stores, Inc.

Johnson Corporation, owner of the registered trademark SUDAFED PE® SINUS CONGESTION.  $\pm 0.844$  ORG082045307 This product is not manufactured or distributed by Johnson &

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hours. Do not take more than 6 tablets in 24 hours. ■ adults and children 12 years and over: take 1 tablet every 4

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

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

Drug Facts (continued)

- symptoms do not improve within 7 days or occur with fever
  - nervousness, dizziness, or sleeplessness occur

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  - thyroid disease high blood pressure
    - diabetes ■ heart disease

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Warnings

- femboratily relieves sinus congestion and pressure usy lever or other upper respiratory allergies
- temporarily relieves nasal congestion due to the common cold,

Nasal decongestant Purpose

Phenylephrine HCl 10 mg ... Active ingredient (in each tablet)

СОМРГЕТЕ РВОDUCT ІНГОЯМАТІОН KEEP OUTER PACKAGE FOR Drug Facts

Sound Body 44-453

#### SINUS CONGESTION PE

phenylephrine hcl tablet, film coated

50844 ന No Print/No varnish Area

44307



#### **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:50844-443

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: M280L1HH48)	

DEXTROSE MONOHYDRATE (UNII: LX22YL083G)

DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)

FD&C RED NO. 40 (UNII: WZB9127XOA)

LECITHIN, SOYBEAN (UNII: 1DI56QDM62)

MAGNESIUM STEARATE (UNII: 70097M6I30)

MALTODEXTRIN (UNII: 7CVR7L4A2D)

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)

**SILICON DIOXIDE** (UNII: ETJ7Z6XBU4)

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED (UNII: K6790BS311)

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
<b>1</b> NDC:50844-443-07	2 in 1 CARTON	12/01/2020	09/21/2025
1	18 in 1 BLISTER PACK; Type 0: Not a Combination Product		

#### **Marketing Information**

Marketing	Application Number or Monograph	Marketing Start	Marketing End
Category	Citation	Date	Date
OTC Monograph Drug	M012	12/01/2020	09/21/2025

## **Labeler -** L.N.K. International, Inc. (038154464)

<b>Establishment</b>			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(50844-443) , pack(50844-443)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		832867894	manufacture(50844-443)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		868734088	manufacture(50844-443)

Establishment			
Name	Address	ID/FEI	<b>Business Operations</b>
LNK International, Inc.		117025878	manufacture(50844-443)

Revised: 6/2024 L.N.K. International, Inc.