

SINUS CONGESTION- phenylephrine hcl tablet, film coated
Kroger Company

Kroger 44-453-Sinus Congestion

Active ingredient (in each tablet)

Phenylephrine HCl 10 mg

Purpose

Nasal decongestant

Uses

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

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?

1-800-632-6900

Principal display panel

Kroger®

COMPARE TO the active ingredient of SUDAFED PE® CONGESTION *See bottom panel

NDC 30142-853-07

Maximum Strength

Sinus Congestion

Phenylephrine HCl 10 mg

Nasal Decongestant

NON-DROWSY

RELIEVES:

- Sinus Pressure
- Nasal & Sinus Congestion

actual size

36 TABLETS

Our Pharmacists Recommended

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

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CINCINNATI, OHIO 45202**

**FOR MORE PRODUCT INFORMATION, SCAN UPC
USING YOUR **KROGER APP** OR CALL 800-632-6900**

*Sudafed PE® Sinus Congestion is a registered trademark of Johnson & Johnson Corporation, New Brunswick, NJ 08933. Johnson & Johnson Corporation is not affiliated with the Kroger Co. or this product.

50844 ORG082045307



Maximum Strength

Sinus Congestion

COMPARE TO the active ingredient of SUDAFED PE® SINUS CONGESTION *See bottom panel

NDC 30142-853-07



Maximum Strength

Sinus Congestion

Phenylephrine HCl 10 mg
Nasal Decongestant

NON-DROWSY

RELIEVES:

Sinus Pressure
Nasal & Sinus Congestion

actual
size



36 TABLETS



85% SIZE
12-digit UPC-A
(non-suppressed)
For Position Only

0 41260 01216 7

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



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50844 ORG082045307

B-1050-453-07-RR
ORG082045307

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

Drug Facts Drug Facts (continued)	Drug Facts Phenylephrine HCl 10 mg Nasal decongestant
Purpose 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.	Uses ■ temporarily relieves sinus congestion and pressure ■ temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
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	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
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	When using this product do not exceed recommended dosage. ■ symptoms do not improve within 7 days or occur with fever ■ nervousness, dizziness, or sleeplessness occur Stop use and ask a doctor if
Inactive ingredients croscarmellose sodium, dextrose monohydrate, dibasic calcium phosphate dihydrate, FD&C red #40, lecithin, magnesium stearate, maltodextrin, microcrystalline cellulose, sodium dioxide, sodium dioxite, titanium dioxide	
Questions or comments? 1-800-632-6900	

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Kroger 44-453

SINUS CONGESTION

phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-853
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
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
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: K679OBS311)	
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:30142-853-07	2 in 1 CARTON	03/19/2021	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:30142-853-23	3 in 1 CARTON	03/19/2021	
2		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing	Application Number or Monograph	Marketing Start	Marketing End
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Category	Citation	Date	Date
OTC Monograph Drug	M012	03/19/2021	

Labeler - Kroger Company (006999528)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(30142-853) , pack(30142-853)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(30142-853)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(30142-853)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(30142-853)

Revised: 3/2024

Kroger Company