

NASAL DECONGESTANT PE, NON-DROWSY- phenylephrine hcl tablet, film coated
CVS PHARMACY

CVS 44-453 - Nasal Decongestant

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

♥CVSHealth®

Compare to the active ingredient
in Sudafed PE® Congestion*

Non-Drowsy Nasal Decongestant PE

PHENYLEPHRINE HCl TABLETS
Nasal decongestant

MAXIMUM STRENGTH

Relieves:

- Sinus pressure
- Nasal congestion

72 TABLETS 10 mg EACH

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® Congestion.

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One CVS Drive, Woonsocket, RI 02895

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Money Back Guarantee

Non-Drowsy
Nasal Decongestant PE
 PHENYLEPHRINE HCl TABLETS - Nasal decongestant
MAXIMUM STRENGTH



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<p>Drug Facts (continued)</p> <p>Active ingredient (in each tablet) Phenylephrine HCl 10 mg Nasal decongestant</p> <p>Purpose Temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies</p> <p>Uses Temporarily relieves sinus congestion and pressure</p> <p>Warnings Do not use if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychotropic 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.</p> <p>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</p> <p>When using this product do not exceed recommended dosage. Stop use and ask a doctor if ■ symptoms do not improve within 7 days or occur with fever</p>	<p>Directions ■ adults and children 12 years and over: take 1 tablet every 4 hours. Do not take more than 6 tablets in 24 hours.</p> <p>Other information ■ TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR BLISTER IS TORN OR BROKEN</p> <p>Inactive ingredients croscarmellose sodium, dextrose monohydrate, dibasic calcium phosphate dihydrate, FD&C red #40, lecithin, magnesium stearate, malto-dextrin, microcrystalline cellulose, silicon dioxide, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide</p> <p>Questions or comments? 1-800-426-9391</p>
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NO PRINT / NO VARNISH AREA
 LOT NO. & EXP. DATE

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CVS Quality
 Money Back Guarantee

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

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

CVS Health.
 Non-Drowsy
Nasal Decongestant PE
 PHENYLEPHRINE HCl TABLETS - Nasal decongestant
MAXIMUM STRENGTH

CVS Health.
 Compare to the active ingredient in Sudafed PE® Sinus Congestion*

Non-Drowsy
Nasal Decongestant PE

PHENYLEPHRINE HCl TABLETS
 Nasal decongestant
MAXIMUM STRENGTH

- Relieves:**
- Sinus pressure
 - Nasal congestion

72 TABLETS 10 mg EACH



44-453

NASAL DECONGESTANT PE, NON-DROWSY
 phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-863
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)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
LECITHIN, SOYBEAN (UNII: 1DI56QDM62)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
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:69842-863-44	1 in 1 CARTON	06/18/2020	
1		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:69842-863-07	2 in 1 CARTON	06/18/2020	
2		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:69842-863-23	3 in 1 CARTON	06/18/2020	
3		24 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	06/18/2020	

Labeler - CVS PHARMACY (062312574)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(69842-863) , pack(69842-863)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(69842-863)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(69842-863)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(69842-863)

Revised: 4/2024

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