

NASAL DECONGESTANT PE- phenylephrine hcl tablet, film coated
Walgreen Company

Walgreens 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°-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

Walgreens

Compare to the active ingredient in
Sudafed PE® Sinus Congestion ††

NDC 0363-4531-07

NON-DROWSY

Nasal Decongestant PE

PHENYLEPHRINE HCl 10 mg / NASAL DECONGESTANT

Maximum Strength

- Relieves sinus pressure & congestion
- Pseudoephedrine free

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

†Our pharmacists recommend the
Walgreens brand. We invite you to

compare to national brands.

††This product is not manufactured or distributed by Johnson & Johnson Corporation, owner of the registered trademark Sudafed PE® Sinus Congestion.

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No print area
Lot no/Exp date

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

Drug Facts 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 ■ symptoms do not improve within 7 days or occur with fever ■ nervousness, dizziness, or sleeplessness occur
Drug Facts (continued) 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 Poison Control Center right away.	Directions adults and children 12 years and over: take 1 tablet every 4 hours. children under 12 years: ask a doctor. Do not take more than 6 tablets in 24 hours.	Other information TAMPER EVIDENT: DO NOT USE IF OUTER PACKAGE IS OPENED OR ALUSTER 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, malto-dextrin, microcrystalline cellulose, silicon dioxide, sodium carboxymethylcellulose, sodium citrate dihydrate, titanium dioxide	(Questions or comments?) 1-800-426-9391

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

B-2201-453-07-4R
ORG082045307



NDC 0363-4531-07



Compare to the active ingredient in Sudafed PE® Sinus Congestion™

NON-DROWSY Nasal Decongestant PE

PHENYLEPHRINE HCl 10 mg / NASAL DECONGESTANT

Maximum Strength

- Relieves sinus pressure & congestion
- Pseudoephedrine free

36 TABLETS



Walgreens 44-453

NASAL DECONGESTANT PE
phenylephrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-4531
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:0363-4531-02	1 in 1 CARTON	01/21/2022	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0363-4531-44	1 in 1 CARTON	01/21/2022	
2		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0363-4531-23	4 in 1 CARTON	01/21/2022	
3		18 in 1 BLISTER PACK; Type 0: Not a Combination Product		
4	NDC:0363-4531-07	2 in 1 CARTON	01/21/2022	
4		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	01/21/2022	

Labeler - Walgreen Company (008965063)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	manufacture(0363-4531) , pack(0363-4531)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	manufacture(0363-4531)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	manufacture(0363-4531)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		117025878	manufacture(0363-4531)

Revised: 1/2024

Walgreen Company