

SINUS CONGESTION PE- guaifenesin and phenylephrine hcl tablet

Rite Aid Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Rite Aid 44-542

Active ingredients (in each immediate-release tablet)

Guaifenesin 400 mg

Phenylephrine HCl 10 mg

Purpose

Expectorant

Nasal decongestant

Uses

- helps loosen phlegm (mucus) and thin bronchial secretions to rid the bronchial passageways of bothersome mucus and make coughs more productive
- temporarily relieves nasal congestion due to the common cold, hay fever or other upper respiratory allergies
- promotes nasal and/or sinus drainage
- 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
- high blood pressure
- thyroid disease
- diabetes
- difficulty urinating due to an enlarged prostate gland
- persistent or chronic cough such as occurs with smoking, asthma, chronic bronchitis, or emphysema
- cough accompanied by too much phlegm (mucus)

When using this product

do not exceed recommended dosage.

Stop use and ask a doctor if

- you get nervous, dizzy or sleepless
- cough comes back or worsens
- symptoms do not improve within 7 days, come back or occur with fever, rash or persistent headache.

These could be signs of a serious condition.

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 of age and older: take 1 tablet every 4 hours, with a full glass of water, while symptoms persist. Do not exceed 6 tablets in 24 hours.
- children under 12 years of age: do not use

Other information

- 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

hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol, povidone, silicon dioxide, sodium starch glycolate, stearic acid

Principal Display Panel

RITE

AID®

PHARMACY

mucus relief

sinus

congestion PE

guaifenesin 400 mg

phenylephrine HCl 10 mg

expectorant

& nasal decongestant

relieves sinus congestion

thins and loosens mucus

ACTUAL

SIZE

IMMEDIATE RELEASE

30 TABLETS

**TAMPER EVIDENT: DO NOT USE IF IMPRINTED
SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

50844 REV0612A54201

DISTRIBUTED BY: RITE AID

30 HUNTER LANE

CAMP HILL, PA 17011

RITE AID®
SATISFACTION GUARANTEE
IF YOU'RE NOT
SATISFIED, WE'LL
HAPPILY REFUND
YOUR MONEY.



Rite Aid 44-542

SINUS CONGESTION PE

guaifenesin and phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-0542
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
GUAIFENESIN (UNII: 495W7451VQ) (GUAIFENESIN - UNII:495W7451VQ)	GUAIFENESIN	400 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	10 mg

Inactive Ingredients	
Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6B30)	
MALTO DEXTRIN (UNII: 7CVR7L4A2D)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics			
Color	WHITE	Score	no score
Shape	OVAL	Size	16 mm
Flavor		Imprint Code	44;542
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-0542-1	1 in 1 CARTON	04/15/2006	07/08/2019
1		30 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part341	04/15/2006	07/08/2019

Labeler - Rite Aid Corporation (014578892)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(11822-0542)

Establishment			
Name	Address	ID/FEI	Business Operations

Revised: 8/2016

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