

12 HOUR DECONGESTANT- pseudoephedrine hydrochloride tablet, film coated, extended release

Kroger Company

Kroger Co. 12 Hour Decongestant Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine HCl 120 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
- high blood pressure
- thyroid disease
- diabetes
- trouble urinating due to an enlarged 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 a 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 (1-800-222-1222).

Directions

adults and children 12 years and over	<ul style="list-style-type: none">• take 1 tablet every 12 hours• do not take more than 2 tablets in 24 hours
children under 12 years	do not use this product in children under 12 years of age

Other information

- **each tablet contains:** calcium 45 mg
- store at 20-25°C (68-77°F) in a dry place
- protect from light
- **do not use if blister unit is broken or torn**
- see carton end panel for lot number and expiration date
- this product meets the requirements of USP Drug Release Test 3

Inactive ingredients

carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, titanium dioxide

Questions or comments?

1-800-632-6900

Principal Display Panel

COMPARE TO the active ingredient of SUDAFED® SINUS CONGESTION 12 HOUR CAPLETS

See back panel

NON-DROWSY

SINUS

12 Hour Decongestant

Pseudoephedrine Hydrochloride Extended Release Tablets, 120 mg

Nasal Decongestant

MAXIMUM STRENGTH

Sinus Pressure

Congestion

Our Pharmacists Recommend

20 COATED CAPLETS* 120 mg EACH

*Capsule-Shaped Tablets

actual size

DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202

QUALITY GUARANTEE
www.kroger.com

GLUTEN FREE



****SUDA FED® IS A REGISTERED TRADEMARK OF JOHNSON & JOHNSON CORPORATION, NEW BRUNSWICK, NJ 08933. THE WITH THE KROGER CO. OR THIS PRODUCT.**

Questions or comments? 1-800-632-6900

Inactive ingredients carnauba wax, colloidal silicon dioxide, dibasic calcium phosphate dihydrate, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyisobutylate B, titanium dioxide

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CONVENIENT RE-CLOSING TAB

50114101/101/49

05460 45 C9



NON-DROWSY • SINUS 12 Hour Decongestant

Pseudoephedrine Hydrochloride Extended Release Tablets, 120 mg
Nasal Decongestant

COMPARE TO the active ingredient of SUDA FED® SINUS CONGESTION 12 HOUR CAPLETS
**See back panel

NDC 30142-054-60



NON-DROWSY • SINUS 12 Hour Decongestant

Pseudoephedrine Hydrochloride Extended Release Tablets, 120 mg
Nasal Decongestant

MAXIMUM STRENGTH

- Sinus Pressure
- Congestion



20 COATED CAPLETS*
120 mg EACH *Capsule-Shaped Tablets

12 HOUR DECONGESTANT

pseudoephedrine hydrochloride tablet, film coated, extended release

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30 142-054
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6 V9 V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DDI9F)	PSEUDOEPHEDRINE HYDROCHLORIDE	120 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	L054
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30 142-054-60	20 in 1 CARTON	03/11/2004	
1		1 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
ANDA	ANDA075153	12/14/1999	

Labeler - Kroger Company (006999528)

Revised: 5/2019

Kroger Company