LEADER NASAL DECONGESTANT- pseudoephedrine hcl tablet, film coated Cardinal Health 110, LLC. dba Leader

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.

Cardinal Health Nasal Decongestant Drug Facts

Active ingredient (in each tablet)

Pseudoephedrine HCl 30 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
- 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	 take 2 tablets every 4 to 6 hours do not take more than 8 tablets in 24 hours
children ages 6 to 11 years	 take 1 tablet every 4 to 6 hours do not take more than 4 tablets in 24 hours
children under 6 years	do not use this product in children under 6 years of age

Other information

- each tablet contains: calcium 20 mg
- store at 20°-25°C (68°-77°F)
- · do not use if blister unit is broken or torn

Inactive ingredients

carnauba wax, dibasic calcium phosphate dihydrate, FD&C red no. 40 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polysorbate 80, silicon dioxide, titanium dioxide

Questions or comments?

1-800-719-9260

Principal Display Panel

LEADER™

Maximum Strength | Non-Drowsy

Nasal Decongestant

Pseudoephedrine HCl Tablets, 30 mg | Nasal Decongestant

Sinus Pressure + Congestion

24 TABLETS

Actual Size

COMPARE TO SUDAFED® CONGESTION MAXIMUM STRENGTH active ingredient* 100% Money Back Guarantee



Important Read all product information before using. Keep this box for important information

Drug Facts Active ingredient (in each tablet) Purpose

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Drug Facts (continued)

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- in 24 hours children under do not use this product in children 6 years under 6 years of age

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Questions or comments? 1-800-719-9260

This product is not man ufactured or distributed by McNeil Con sumer Health care, distribut or of Sudafed® Congestion Maximum Strength.





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LEADER NASAL DECONGESTANT

pseudoephedrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0002
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Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

POLYSORBATE 80 (UNII: 60ZP39ZG8H)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	

Product Characteristics				
Color	RED	Score	no score	
Shape	ROUND (convex)	Size	7mm	
Flavor		Imprint Code	L432	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000- 0002-1	24 in 1 CARTON	12/20/2019	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:70000- 0002-2	8 in 1 CARTON	01/16/2020	
2		12 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 final	part341	12/20/2019	

Labeler - Cardinal Health 110, LLC. dba Leader (063997360)

Revised: 12/2021 Cardinal Health 110, LLC. dba Leader