

**CAREONE NASAL AND SINUS DECONGESTANT- pseudoephedrine hcl tablet, film coated
American Sales Company**

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.

American Sales Company Nasal & Sinus 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	<ul style="list-style-type: none">• take 2 tablets every 4 to 6 hours• do not take more than 8 tablets in 24 hours
children ages 6 to 11 years	<ul style="list-style-type: none">• 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

Compare to the active ingredient in Sudafed® Congestion

NASAL & SINUS DECONGESTANT

Pseudoephedrine HCl Tablets, 30 mg

Nasal Decongestant

Maximum Strength

Sinus Pressure

Congestion

Non-Drowsy

Actual Size

OUR PHARMACISTS RECOMMEND

24 TABLETS

30 mg EACH



CAREone[®]

NDC 41520-881-62

Compare to the active ingredient in
Sudafed[®] Congestion*

NASAL & SINUS DECONGESTANT

Pseudoephedrine HCl Tablets, 30 mg
Nasal Decongestant

Maximum Strength

- Sinus Pressure
- Congestion

Non-Drowsy

Actual Size



24 TABLETS
30 mg EACH





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

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Drug Facts (continued)

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*This product is not manufactured or distributed by McNeil Consumer Healthcare, distributor of Sudafed® Congestion. Gluten Free

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CAREONE NASAL AND SINUS DECONGESTANT

pseudoephedrine hcl tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-881
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PSEUDOEPHEDRINE HYDROCHLORIDE (UNII: 6V9V2RYJ8N) (PSEUDOEPHEDRINE - UNII:7CUC9DD19F)	PSEUDOEPHEDRINE HYDROCHLORIDE	30 mg

Inactive Ingredients

Ingredient Name	Strength
CARNAUBA WAX (UNII: R12CBM0EIZ)	
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	

MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
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:41520-881-62	2 in 1 CARTON	09/25/2017	
1		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:41520-881-67	4 in 1 CARTON	09/25/2017	
2		12 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:41520-881-80	8 in 1 CARTON	09/25/2017	
3		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	09/25/2017	

Labeler - American Sales Company (809183973)