

SINUS HEADACHE PE NON- DROWSY MAXIMUM STRENGTH- acetaminophen and phenylephrine hcl tablet
American Sales Company

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 325mg
Phenylephrine HCl 5mg

Purpose

Pain reliever
Nasal decongestant

Uses

temporarily relieves:

- nasal and sinus congestion
- minor aches and pains, headaches

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 8 caplets in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include ■ skin reddening ■ blisters ■ rash
If a skin reaction occurs, stop use and seek medical help right away.

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 ■ with other products containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if you have

■ liver disease ■ heart disease ■ high blood pressure ■ thyroid disease ■ diabetes ■ trouble urinating due to an enlarged prostate

Ask a doctor or pharmacist before use if you are

taking the blood thinning drug warfarin.

When using this product

do not use more than directed.

Stop use and ask a doctor if

■ redness or swelling is present ■ new symptoms occur ■ you get nervous, dizzy or sleepless ■ pain gets worse or lasts more than 7 days ■ fever gets worse or lasts more than 3 days ■ **You may report side effects to 1-888-952-0050**

If pregnant or breast-feeding,

ask a health professional before use.

Keep out of reach of children.

In case of accidental overdose, contact a doctor or Poison Control Center (1-800-222-1222) immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms

Directions

- Adults and children 12 years of age and older: take 2 tablets every 4-6 hours
- Do not take more than 8 tablets in 24 hours
- Do not use in children under 12 years of age. This will provide more than the recommended dose (overdose) and could cause serious health problems

Other Information

- store at room temperature in a dry place
- do not use if blister package is torn

Inactive ingredients

corn starch, crospovidone, FD&C yellow #6 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid, titanium dioxide

Package/Label Principal Display Panel

CareOne®

Compare to the active ingredient in Sudafed PE® PRESSURE + PAIN**

SINUS PRESSURE + PAIN PE

Pain Reliever - Acetaminophen

Nasal Decongestant - Phenylephrine HCl

Max Strength

Relieves:

Sinus Pain & Headache

Sinus Pressure

Nasal & Sinus Congestion

Does not contain pseudoephedrine

NON-DROWSY

24

COATED CAPLETS*

*Capsule - Shaped Tablets

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LANDOVER, MD 20785 1-877-846-9949

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Care One Sinus Pressure + Pain PE

SINUS HEADACHE PE NON- DROWSY MAXIMUM STRENGTH

acetaminophen and phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41520-270
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSPROVIDONE (12 MPA.S AT 5%) (UNII: 40UAA97IT9)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	

Product Characteristics

Color	orange	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	AZ270
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41520-270-24	24 in 1 BLISTER PACK; Type 0: Not a Combination Product	06/12/2014	07/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	06/12/2014	07/31/2024

Labeler - American Sales Company (809183973)

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American Sales Company