

SINUS HEADACHE PEMAXIMUM STRENGTH NON-DROWSY MAXIMUM STRENGTH NON-DROWSY- acetaminophen and phenylephrine hcl tablet
Allegiant Health

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 325 mg
Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer
Nasal decongestant

Uses

temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold:

- sinus congestion and pressure
- headache
- minor aches and pains
- nasal congestion
- promotes sinus drainage
- temporarily reduces fever

Warnings

Liver warning/Allergy alert

Liver warning: This product contains acetaminophen.

Severe liver damage may occur if you take

- more than 4,000mg of acetaminophen in 24 hours
- 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

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- 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 using this product.
- if you have ever had an allergic reaction to this product or any of its ingredients

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

When using this product do not exceed recommended dose

Stop use and ask a doctor if

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur
- **You may report side effects to 1-888-952-0050**

If pregnant or breast-feeding

If pregnant or breast-feeding, ask a health professional before use.

Keep Out of Reach of Children

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

do not use more than directed (see overdose warning)

adults and children 12 years of age and older:

- take 2 caplets every 4-6 hours

- do not take more than 10 caplets in 24 hours

children under 12 years:

- ask a doctor

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

HealthA2Z[®] Non-Drowsy Sinus Headache PE



HealthA2Z[®]

*Compare to the active ingredient in Sudafed PE[®] Pressure + Pain

MAXIMUM STRENGTH

Non-Drowsy Sinus Headache PE

Acetaminophen 325mg • Phenylephrine 5 mg

Does not contain Pseudoephedrine

- Sinus Pain & Headache
 - Sinus Pressure
 - Nasal & Sinus Congestion
- See new warnings information



18 Caplets

Lot:
Exp:

*This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark SUDAFED PE[®] PRESSURE+PAIN.

LB0266
R0318

Manufactured by:
Allegiant Health
Deer Park, NY



3 69168 27095 4

Non-Drowsy Sinus Headache PE

<p>Drug Facts (continued)</p> <p>Drug Facts</p> <p>Active ingredient (in each caplet) Acetaminophen 325mg.....Pain reliever/fever reducer Phenylephrine HCl 5mg.....Nasal decongestant</p> <p>Purpose temporarily relieves these symptoms associated with hay fever or other upper respiratory allergies, and the common cold: sinus congestion and pressure ■ headache ■ minor aches and pains ■ nasal congestion ■ temporarily reduces fever</p> <p>Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 4,000mg of acetaminophen in 24 hours ■ 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.</p> <p>Do not use ■ with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. ■ 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 using this product. ■ if you have ever had an allergic reaction to this product or any of its ingredients</p> <p>Inactive ingredients corn starch, croscaps, FD&C yellow #6 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid, titanium dioxide</p>	<p>Directions do not use more than directed (see overdose warning) adults and children 12 years of age and older: ■ take 2 caplets every 4-6 hours ■ do not take more than 10 caplets in 24 hours children under 12 years: ■ ask a doctor</p> <p>Other information ■ store between 20-25°C (68-77°F) ■ do not use if blister unit is torn or open</p> <p>Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.</p> <p>Stop use and ask a doctor if ■ nervousness, dizziness, or sleeplessness occur ■ pain or nasal congestion 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</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p>
---	--

Sinus Headache

SINUS HEADACHE PEMAXIMUM STRENGTH NON-DROWSY MAXIMUM STRENGTH NON-DROWSY

acetaminophen and phenylephrine hcl tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-270
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)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSPVIDONE (UNII: 2S7830E561)	

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:69168-270-95	18 in 1 BLISTER PACK; Type 0: Not a Combination Product	12/22/2014	10/31/2027

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	12/22/2014	10/31/2027

