

**FIRST AID DIRECT HEADACHE AND CONGESTION SINUS RELIEF-
acetaminophen phenylephrine hcl tablet
Cintas Corporation**

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.

First Aid Direct Headache and Congestion Sinus Relief

Active ingredients (in each tablet)

Acetaminophen 500 mg

Phenylephrine HCl 5 mg

Purpose

Pain reliever/fever reducer

Nasal decongestant

Uses

temporarily relieves these symptoms associated with hay fever or other 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: This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- adult has 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.
- 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.

- if you are allergic to acetaminophen or any of the inactive ingredients in this product.

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 gland

Ask a doctor before use if you are taking the blood thinning drug warfarin.

Stop use and ask doctor if

- nervousness, dizziness, or sleeplessness occur
- pain or nasal congestion gets worse or lasts more than 7 days
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- redness or swelling is present
- new symptoms occur

These could be signs of a serious condition.

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

Keep out of reach of children.

Overdose warning: 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

- adults and children 12 years and older: • take 2 tablets every 6 hours • do not take more than 8 tablets in 24 hours
- children under 12 years of age: ask a doctor

Other information

- store at room temperature between 20-25°C (68-77°F)
- do not use if packet is open or torn

Inactive ingredients

corn starch, crospovidone, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, stearic acid

Questions?

Call 1-800-327-2704 M-F 8AM-5PM

Principal Display Panel - 42961-126-02

HEADACHE & CONGESTION

SINUS RELIEF

Active Ingredients:

Acetaminophen • Phenylephrine HCl

Pain Reliever/Fever Reducer & Nasal Decongestant

- Fast acting relief for nasal and sinus congestion
- Helps reduce sinus pain, pressure, fever, and pain

50 Tablets • 25 Packets (2 Tablets in each packet) per Box

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Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42961-126
Route of Administration	oral		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
PHENYLEPHRINE HYDROCHLORIDE (UNII: 04JA59TNSJ) (PHENYLEPHRINE - UNII:1WS297W6MV)	PHENYLEPHRINE HYDROCHLORIDE	5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSPROVIDONE (UNII: 2S7830E561)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

Product Characteristics

Color	white	Score	no score
Shape	ROUND	Size	12mm
Flavor		Imprint Code	AZ261
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:42961-126-02	25 in 1 BOX	09/26/2023	
1	NDC:42961-126-01	2 in 1 PACKET; 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	09/26/2023	

Labeler - Cintas Corporation (056481716)

Establishment

Name	Address	ID/FEI	Business Operations
Allegiant Health		079501930	manufacture(42961-126)

Revised: 9/2023

Cintas Corporation