

HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin and caffeine tablet, film coated
Allegiant Health

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 250 mg
Aspirin 250 mg (NSAID*)
Caffeine 65 mg

* nonsteroidal anti-inflammatory drug

Purpose

Pain reliever
Pain reliever
Pain reliever aid

Uses

temporary relief of minor aches and pains associated with ■ headache ■ common cold ■ sinusitis ■ toothache ■ muscular aches ■ arthritis ■ premenstrual and menstrual cramps

Warnings

Reye's syndrome: Children and teenagers who have or are recovering from chicken pox or flu-like symptoms should not use this product. When using this product, if changes in behavior with nausea and vomiting occur, consult a doctor because these symptoms could be an early sign of Reye's syndrome, a rare but serious illness.

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.

Allergy alert: Aspirin may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Liver warning: This product contains acetaminophen. Severe liver damage may occur if

- adult takes more than 8 tablets in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 3 or more alcoholic drinks every day while using this product

Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Caffeine warning: The recommended dose of this product contains about as much caffeine as a cup of coffee. Limit the use of caffeine-containing medications, foods, or beverages while taking this product because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heart beat.

Do not use

- if you have ever had an allergic reaction to acetaminophen, aspirin or any other pain reliever/fever reducer
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

Ask doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic
- you have asthma

Ask a doctor or pharmacist before use if you are taking

- any other drug containing an NSAID (prescription or nonprescription)
- a blood thinning (anticoagulant) or steroid drug
- a prescription drug for diabetes, gout, or arthritis
- any other drug, or are under a doctor's care for any serious condition

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away
- you feel faint, vomit blood, have bloody or black stools. These are signs of stomach bleeding.
- stomach pain or upset gets worse or lasts
- ringing in ears or loss of hearing occurs

- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- painful area is red or swollen
- new symptoms occur

If pregnant or breast-feeding

ask a health professional before use. It is especially important not to use aspirin during the last 3 months of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center immediately. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

Do not exceed recommended dosage.

Drink a full glass of water with each dose.

Adults and children 12 years and over: take 2 tablets every 6 hours. Do not take more than 8 tablets in 24 hours.

Children under 12 years: ask a doctor

Other information

- store at 20°-25°C (68°-77°F)
- keep carton for full product information
- **do not use if imprinted safety seal under cap is broken or missing**
- **you may report serious side effects to 1-888-952-0050**

Inactive Ingredients

corn starch, croscarmellose sodium, crospovidone, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, silicon dioxide, stearic acid, titanium dioxide

Package/Label Principal Display Panel

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	

Product Characteristics

Color	white (White)	Score	no score
Shape	CAPSULE (Capsule shaped tablet)	Size	18mm
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-285-24	1 in 1 CARTON	02/15/2010	03/31/2024
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:69168-285-37	1 in 1 CARTON	09/08/2022	
2		16 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020802	02/15/2010	

Labeler - Allegiant Health (079501930)