

ACETAMINOPHEN ASPIRIN CAFFEINE- acetaminophen aspirin caffeine tablet
CVS PHARMACY, INC

Migraine Relief

ACETAMINOPHEN, ASPIRIN (NSAID), CAFFEINE TABLETS, USP

PAIN RELIEVER/PAIN RELIVER AID

Active ingredients (in each caplet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)**

Caffeine 65 mg

**nonsteroidal anti-inflammatory drug

Purposes

Pain reliever

Pain reliever aid

Use

treats migraine

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 you take

- more than 2 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

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

Medication overuse headache warning:

Headaches may worsen if this product is used for 10 or more days per month.

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 a doctor before use if

- you have never had migraines diagnosed by a health professional
- you have a headache that is different from your usual migraines
- you have the worst headache of your life
- you have fever and stiff neck
- you have headaches beginning after or caused by head injury, exertion, coughing or bending
- you experienced your first headache after the age of 50
- you have daily headaches

- you have a migraine so severe as to require bed rest
- 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
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have vomiting with your migraine headache

Ask a doctor or pharmacist before use if you are

- taking a prescription drug for:
 - diabetes • gout • arthritis
- under a doctor's care for any serious condition
- taking any other drug
- taking any other product that contains aspirin, acetaminophen or any other pain reliever/fever reducer

Stop use and ask a doctor if

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- you experience any of the following signs of stomach bleeding:
 - feel faint • vomit blood • have bloody or black stools • have stomach pain that does not get better
- your migraine is not relieved or worsens after first dose
- new or unexpected symptoms occur
- ringing in the ears or loss of hearing occurs

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 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
- adults: take 2 caplets with a glass of water
 - if symptoms persist or worsen, ask your doctor



ACETAMINOPHEN ASPIRIN CAFFEINE

acetaminophen aspirin caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69842-680
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	Strength
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SODIUM STEARYL FUMARATE (UNII: 7CV7WJK4UI)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

Product Characteristics			
Color	white	Score	no score
Shape	CAPSULE (Capsule shaped Tablet)	Size	17mm
Flavor		Imprint Code	l1
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69842-680-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/05/2021	

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214039	07/05/2021	

Revised: 12/2023

CVS PHARMACY, INC