

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

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

- do not take more than 2 caplets in 24 hours, unless directed by a doctor
- under 18 years of age: ask a doctor

Other information

- store at room temperature 20° to 25°C (68° to 77°F)
- close cap tightly after use
- read all product information before using.

Inactive ingredients

carnauba wax, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, sodium stearyl fumarate and titanium dioxide

Questions or comments?

Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.

COATING
FREE AREA

700000002504
20000003351

PANTONE 301
PANTONE 386
CVS CARDINAL

Drug Facts (continued)
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
if with any other drug containing acetaminophen (prescription or nonprescription), if you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist
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if you have asthma
if you have problems or serious side effects from taking pain relievers or fever reducers
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Ask a doctor or pharmacist before use if you are
taking a prescription drug for:
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taking any other drug
taking any other product that contains aspirin, acetaminophen or any other pain reliever/fever reducer

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COATING
FREE AREA

100 CAPLETS*
Capsule-Shaped Tablets

Actual Size

Package
One Bottle

Migraine Relief
ACETAMINOPHEN, ASPIRIN (NSAID)
& CAFFEINE TABLETS, USP
Pain reliever/Pain reliever aid

CVS Health.

Compare to the active ingredients of Excedrin® Migraine* Caplets*

#695036

50428 31887 4

Lot
Exp.

COATING
FREE AREA

COATING
FREE AREA

700000002504
20000003351

PANTONE 301
PANTONE 386
CVS CARDINAL

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if symptoms persist or worsen, ask your doctor
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under 18 years of age: ask a doctor
Other information
store at room temperature 20° to 25°C (68° to 77°F)
close cap tightly after use
read all product information before using.
Inactive ingredients: carnauba wax, hydroxypropyl cellulose, hypromellose, microcrystalline cellulose, polyethylene glycol, sodium stearyl fumarate and titanium dioxide
Questions or comments?
Contact 1-877-770-3183 Mon-Fri 8:00 AM EST to 5:00 PM PST.
*This product is not manufactured or distributed by GSK Consumer Healthcare, distributor of Excedrin® Migraine.

COATING
FREE AREA

end user : GRANULES

item :

code # :

size : 2x3/32 X 2x3/32 X 4x3/16

ref # : PFI80604A view :

material : 016 SBS date :

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	

Labeler - CVS PHARMACY, INC (062312574)

