

**ACETAMINOPHEN ASPIRIN CAFFEINE- acetaminophen aspirin caffeine tablet  
WALGREEN CO**

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**Migraine Relief  
ACETAMINOPHEN, ASPIRIN (NSAID), CAFFEINE TABLETS  
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.





## ACETAMINOPHEN ASPIRIN CAFFEINE

acetaminophen aspirin caffeine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-9680
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B6978945GQ)	
<b>HYDROXYPROPYL CELLULOSE (110000 WAMW)</b> (UNII: 5Y0974F5PW)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	

<b>SODIUM STEARYL FUMARATE</b> (UNII: 7CV7WJK4UI)	
<b>HYPROMELLOSE 2910 (6 MPA.S)</b> (UNII: 0WZ8WG20P6)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Capsule shaped Tablet)	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	I1
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-9680-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	08/16/2021	
2	NDC:0363-9680-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	08/16/2021	03/31/2023

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214039	08/16/2021	

**Labeler** - WALGREEN CO (008965063)

Revised: 4/2024

WALGREEN CO