

## **HEADACHE RELIEF EXTRA STRENGTH- acetaminophen, aspirin, caffeine tablet Walgreens**

*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.*

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### **Drug Facts**

#### **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

### **Uses**

- temporarily relieves minor aches and pains due to:
  - headache
  - a cold
  - arthritis
  - muscular aches
  - toothache
  - 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
- shock
- asthma (wheezing)

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

- more than 8 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

**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 heartbeat.

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

### **Ask a doctor or pharmacist before use if you are**

- taking a prescription drug for diabetes, gout, or arthritis
- taking any other drug, or are under a doctor's care for any serious condition

### **Stop use and ask doctor if**

- an allergic reaction occurs, Seek medical help right away

- any new symptoms appear.
- 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
- ringing in the 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

these could be signs of a serious condition.

### **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**
- drink a full glass of water with each dose
- adults and children 12 years and over: take 2 caplets every 6 hours; do not take more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

### **Other information**

- store between 20°-25°C (68°-77°F)

### **Inactive ingredients**

colloidal silicon dioxide, corn starch, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid, talc

### **Questions or comments?**

Call **1-877-753-3935** Monday-Friday 9AM-5PM EST

### **Principal Display Panel**

Compare to the active ingredients in Excedrin® Extra Strength††

Headache Relief

ACETAMINOPHEN / ASPIRIN (NSAID)

PAIN RELIEVER / CAFFEINE / PAIN RELIEVER AID

EXTRA STRENGTH

CAPLETS

††This product is not manufactured or distributed by GSK Consumer Healthcare distributor of Excedrin® Extra Strength.

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.**

DISTRIBUTED BY: WALGREENS CO., 200 WILMOT RD., DEERFIELD, IL 60015

### Package Label

**VALUE SIZE** NDC 0363-1150-25

**Walgreens**

Compare to the active ingredients in Excedrin® Extra Strength††

**Headache Relief**

ACETAMINOPHEN / ASPIRIN (NSAID) / PAIN RELIEVER / CAFFEINE / PAIN RELIEVER AID

**EXTRA STRENGTH**

**CAPLETS**

**250 CAPLETS** ACTUAL SIZE

**TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING**

**Drug Facts**

**Active ingredients (in each caplet)**

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

\*nonsteroidal anti-inflammatory drug

**Uses**

- Temporarily relieves minor aches and pains due to:
  - headache
  - cold
  - arthritis
  - muscular aches
  - toothache
- premenstrual and menstrual cramps

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

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- skin redness
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

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**Drug Facts (continued under label)**

Walgreens Pharmacist Recommended  
Walgreens Pharmacist Survey

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**PEEL HERE**

**Drug Facts (continued)**

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**Stop use and ask a doctor if**

- an allergic reaction occurs. Seek medical help right away.
- any new symptoms appear
- you experience any of the following signs of stomach bleeding:
  - heart burn
  - vomit blood
  - have bloody or black stools
  - have stomach pain that does not get better
  - ringing in the ears or loss of hearing occurs
  - pain gets worse or lasts for more than 10 days
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**Other information**

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**Inactive ingredients** colloidal silicon dioxide, corn starch, hypromellose, microcrystalline cellulose, polyethylene glycol, povidone, stearic acid, talc.

**Questions or comments?**  
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**WALGREENS Headache Relief Extra Strength**

**HEADACHE RELIEF EXTRA STRENGTH**

acetaminophen, aspirin, caffeine tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0363-1150
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	S53
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-1150-25	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/30/2020	

## Marketing Information

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
OTC monograph not final	part343	07/30/2020	

**Labeler** - Walgreens (008965063)

