

## **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
  - sinusitis
  - 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:** 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**

- you experience any of the following signs of stomach bleeding:
  - feel faint
  - have bloody or black stools
  - vomit blood
  - have stomach pain that does not get better
- an allergic reaction occurs. Seek medical help right away.
- any new symptoms appear
- 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

**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: do not use unless directed by a doctor

### **Other information**

- store at controlled room temperature 20°-25°C (68°-77°F)

### **Inactive ingredients**

carnauba wax\*\*, colloidal silicon dioxide, corn starch, hypromellose, maltodextrin\*\*, microcrystalline cellulose, mineral oil\*\*, polydextrose\*\*, povidone, sodium starch glycolate\*\*, stearic acid, talc\*\*, titanium dioxide, triglycerides\*\*

\*\*contains one or more of these ingredients

### **Questions or comments?**

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

### **Principal Display Panel**

Extra Strength

#### **Headache Relief**

Acetaminophen/ Aspirin (NSAID)/Caffeine/ Pain Reliever/Pain Reliever Aid

Caplets

Compare to Excedrin® Extra Strength Caplets active ingredients≠≠

≠≠This product is not manufactured or distributed by Novartis, owner of the registered trademark Excedrin® Extra Strength.

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

DISTRIBUTED BY: WALGREEN CO.

200 WILMOT RD., DEERFIELD, IL 60015

walgreens.com

### **Package Label**

**NEW** Well at Walgreens  
WALGREENS PHARMACIST RECOMMENDED<sup>†</sup>  
**EXTRA STRENGTH**  
**Headache Relief**  
Acetaminophen / Aspirin (NSAID) / Caffeine / Pain Reliever / Pain Reliever Aid  
**250 CAPLETS**  
Compare to Excedrin<sup>®</sup> Extra Strength Caplets active ingredients<sup>‡</sup>

NDC 0363-0247-25

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

**Drug Facts**

**Purposes**  
Acetaminophen 250 mg.....Pain reliever  
Aspirin 250 mg (NSAID)\*.....Pain reliever  
Caffeine 65 mg.....Pain reliever aid  
\*nonsteroidal anti-inflammatory drug

**Uses**  
Temporarily relieves minor aches and pains due to:  
■ arthritis ■ muscular aches ■ sinusitis ■ headache  
■ 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:** 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.

**Drug Facts (continued under label)**

Walgreens Pharmacist Survey Study, November 2012.  
† This product is not manufactured or distributed by Walgreens, one of the registered trademark holders of the Walgreens logo.  
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**Directions**  
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■ 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  
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**Other Information**  
Store at controlled room temperature 20°-25°C (68°-77°F)

**Inactive ingredients**  
carnauba wax, colloidal silicon dioxide, corn starch, hypromellose, maltodextrin, microcrystalline cellulose, mineral oil, polydextrose, povidone, sodium starch glycolate, stearic acid, talc, titanium dioxide, triethylcitrate

**Questions or comments?**  
Call 1-877-753-3935  
Monday-Friday 9AM-5PM EST

**Drug Facts (continued)**  
**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 a doctor if** ■ you experience any of the following signs of stomach bleeding: ■ feel faint ■ have bloody or black stools ■ won't bleed ■ have stomach pain that does not get better ■ an allergic reaction occurs. Seek medical help right away. ■ any new symptoms appear ■ 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  
**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.

**Well at Walgreens Extra Strength Headache Relief Caplets**

HEADACHE RELIEF EXTRA STRENGTH			
acetaminophen, aspirin, caffeine tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0363-0247
Route of Administration	ORAL		
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MALTODEXTRIN (UNII: 7CVR7L4A2D)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
C10-18 TRIGLYCERIDES (UNII: 43AGM4PHP)	

### Product Characteristics

Color	WHITE	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	2793;TCL370
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0363-0247-25	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	09/30/2014	12/31/2019

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH NOT FINAL	part343	09/30/2014	12/31/2019

**Labeler** - Walgreens (008965063)

Revised: 12/2018

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