

**EXTRA STRENGTH HEADACHE RELIEF- acetaminophen, aspirin, and caffeine tablet, coated**  
**Dollar General**

*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.*

-----

**Extra Strength Headache Relief**

**Drug Facts**

<b>Active ingredients (in each caplet)</b>	<b>Purposes</b>
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:

- headache
- a cold
- arthritis
- muscular aches
- toothache
- premenstrual & 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
- asthma (wheezing)
- shock

### **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 occasional 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 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

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

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

**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
- ringing in the ears or loss of hearing occurs
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- any new symptoms occur

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.**

**Overdose warning**

Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away.

**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; not more than 8 caplets in 24 hours
- children under 12 years: ask a doctor

**Other information**

- store at room temperature between 20-25°C (68 to 77°F)
- avoid excessive heat, cold and humidity
- close cap tightly after use
- read all product information before using.

**Inactive ingredients**

croscarmellose, magnesium stearate, microcrystalline cellulose, polacrillin potassium, polyethylene glycol , polyvinyl alcohol, povidone, purified talc, sodium lauryl sulphate, sodium starch glycolate, starch, titanium dioxide

**Questions or comments?**

**1-888-577-8033**

**PRINCIPAL DISPLAY PANEL - 100 Caplet Bottle Carton**

Compare to active ingredients  
in Excedrine® Extra Strength††

NDC XXXXX-XXX-XX

Headache

Relief

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

EXTRA STRENGTH

ACTUAL SIZE

100 CAPLETS

Made in India

EXP:

LOT:

CTXXXXXXX REV.00-030321

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

Distributed by:

ITEM #

UPC

Compare to active ingredients  
in Excedrine® Extra Strength<sup>††</sup>

NDC XXXXX-XXX-XX

# Headache Relief

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

**EXTRA STRENGTH**

**100** CAPLETS



ACTUAL SIZE

**TAMPER EVIDENT: DO NOT USE IF SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.  
KEEP OUTER BOX FOR FULL INFORMATION.**

## Drug Facts

Active ingredients (in each caplet)	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:

■ headache ■ a cold ■ arthritis ■ muscular aches ■ toothache  
■ premenstrual & 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 ■ asthma (wheezing) ■ shock

**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 occasional rapid heart beat.

ORG0219-F

arate,  
lycol,  
e, sodium

### 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 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

**Ask a doctor or pharmacist before use if you are taking** ■ a prescription drug for diabetes, gout, or arthritis ■ any other drug, or are under a doctor's care for any serious condition

#### 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  
■ ringing in the ears or loss of hearing occurs  
■ painful area is red or swollen  
■ pain gets worse or lasts for more than 10 days  
■ fever gets worse or lasts for more than 3 days  
■ any new symptoms occur

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.**

**Overdose warning:** Taking more than directed can cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away.

### Directions

■ do not use more than directed

100  
CAPLETS

EXTRA STRENGTH

**Headache Relief**  
**ACETAMINOPHEN / ASPIRIN (NSAID) / CAFFEINE**  
**PAIN RELIEVER / PAIN RELIEVER AID**

Compare to active ing  
in Excedrine® Extra S

NDC XX

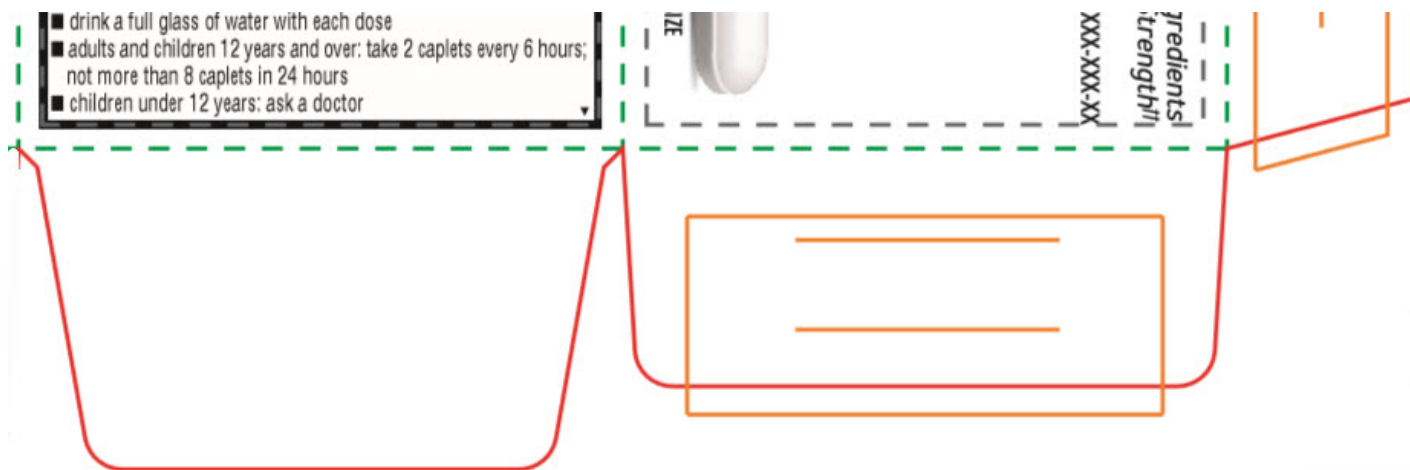
### Drug Facts (continued)

#### Other information

- store at room temperature between 20-25°C (68 to 77°F)
- avoid excessive heat, cold and humidity
- close cap tightly after use
- read all product information before using.

**Inactive ingredients** croscarmellose, magnesium stearate, microcrystalline cellulose, polyacrylin potassium, polyethylene glycol, polyvinyl alcohol, povidone, purified talc, sodium lauryl sulphate, starch, glycolate, starch, titanium dioxide

**Questions or comments?** 1-888-577-8033



## EXTRA STRENGTH HEADACHE RELIEF

acetaminophen, aspirin, and caffeine tablet, coated

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55910-440
Route of Administration	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<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

Ingredient Name	Strength
<b>Croscarmellose</b> (UNII: 029TFK992N)	
<b>Magnesium Stearate</b> (UNII: 70097M6I30)	
<b>Microcrystalline Cellulose</b> (UNII: OP1R32D61U)	
<b>Polacrillin Potassium</b> (UNII: 0BZ5A00FQU)	
<b>Polyethylene Glycol, Unspecified</b> (UNII: 3WJQ0SDW1A)	
<b>Polyvinyl Alcohol, Unspecified</b> (UNII: 532B59J990)	
<b>Talc</b> (UNII: 7SEV7J4R1U)	
<b>Sodium Lauryl Sulfate</b> (UNII: 368GB5141J)	
<b>Sodium Starch Glycolate Type A</b> (UNII: H8AV0SQX4D)	
<b>Titanium Dioxide</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	S142
Contains			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55910-440-01	1 in 1 CARTON	05/01/2021	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/01/2021	

**Labeler** - Dollar General (068331990)

Revised: 4/2021

Dollar General