

**ACETAMINOPHEN, ASPIRIN, CAFFEINE- acetaminophen, aspirin,  
caffeine tablet, film coated  
Cardinal Health**

*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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**5004-Cardinal**

**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 aid

**Uses**

■ temporarily relieves minor aches and pains due to:

■ headache

■ muscular aches

■ a cold

■ arthritis

■ toothache

■ premenstrual and menstrual cramps

**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)

**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.

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take: ■ with other drugs containing acetaminophen ■ more than 8 caplets in 24 hours, which is the maximum daily amount ■ 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 ■ take more or for a longer time than directed ■ 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

**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 a history of stomach problems, such as heartburn

■ you have high blood pressure, heart disease, liver cirrhosis, or kidney disease

■ you have asthma

■ you are taking a diuretic

### **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 ■ vomit blood

■ have stomach pain that does not get better

■ an allergic reaction occurs. Seek medical help right away.

■ 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

■ any new symptoms appear.

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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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 at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- use by expiration date on package

hypromellose, maltodextrin, microcrystalline cellulose, polydextrose, polyvinylpyrrolidone, pregelatinized starch, silica, starch, stearic acid, talc, titanium dioxide, triglycerides

***Questions or comments?***

1-800-231-4670

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

RETAIN THIS CARTON FOR COMPLETE PRODUCT INFORMATION

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

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DUBLIN, OHIO 43017  
1-800-200-6313  
[www.myleader.com](http://www.myleader.com)

Leader

NDC 70000-0066-1

Extra Strength

Headache Relief

Acetaminophen

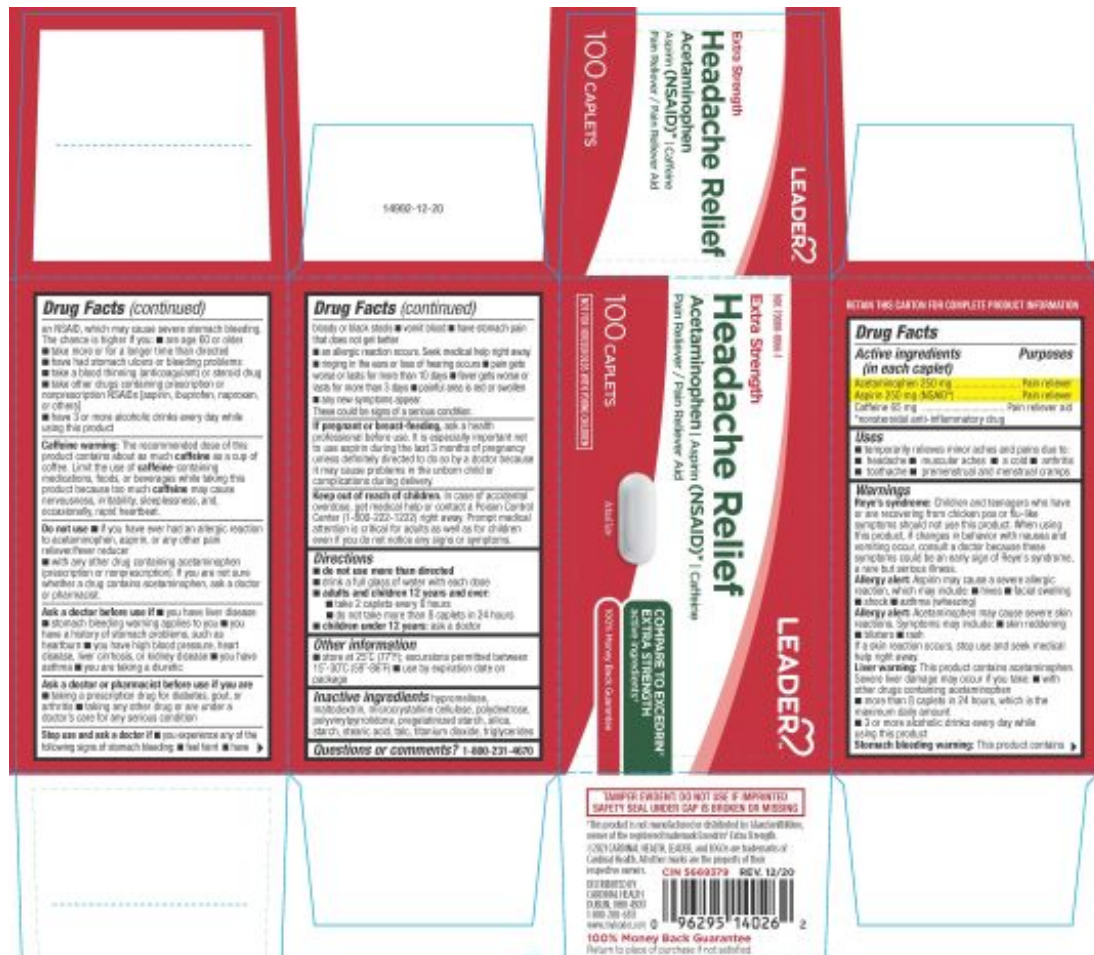
Aspirin (NSAID)\* / Caffeine

Pain Reliever / Pain Reliever Aid

COMPARE TO EXCEDRIN® EXTRA STRENGTH active ingredients†

100 Caplets

NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN



## ACETAMINOPHEN, ASPIRIN, CAFFEINE

acetaminophen, aspirin, caffeine tablet, film coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:70000-0066
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>POLYDEXTROSE</b> (UNII: VH2XOU12IE)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	

## Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	17mm
<b>Flavor</b>		<b>Imprint Code</b>	2793
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0066-1	1 in 1 CARTON	11/06/2020	
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	11/06/2020	

**Labeler** - Cardinal Health (063997360)

Revised: 6/2021

Cardinal Health