

**GENCARE HEADACHE RELIEF- acetaminophen, aspirin, caffeine tablet**  
**Pioneer Life Sciences, LLC**

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**Headache Relief**

**Active Ingredients (in each caplet)**

Acetaminophen 250 mg

Aspirin 250 mg

Caffeine 65 mg

**Purpose**

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, 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 Doctor:**

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 DOCTOR/PHARMACIST:**

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 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 for more than 10 days

■ fever gets worse or lasts more than 3 days

■ any new symptoms occur. These could be signs of a serious condition.

## **PREGNANCY**

**If pregnant or breast-feeding**, ask a health professional before use. It is especially important not to use aspirin at 20 weeks or later in 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 (1-800-222-1222) 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 of age 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 between 20°-25°C (68°-77°F)

■ Close cap tightly after use

■ Read all product information before using.

■ Keep this box for important information.

## INACTIVE INGREDIENTS

Colloidal Silicon Dioxide, Hypromellose, Microcrystalline Cellulose, Polyethylene Glycol, Pregelatinized Starch, Polyvinyl Pyrrolidone, Stearic Acid Powder, Talc.

## QUESTIONS OR COMMENTS?

Call 1-732-698-5070 Monday through Friday 9 AM to 5 PM EST.

## PRINCIPAL DISPLAY PANEL

†compare to EXCEDRIN®  
EXTRA STRENGTH  
active ingredients



**EXTRA STRENGTH**

# Headache Relief

**Pain Reliever / Pain Reliever Aid**

Acetaminophen 250mg  
Aspirin 250mg (NSAID)  
Caffeine 65mg



**300 caplets** not actual size

**TAMPER EVIDENT Do not use if safety seal under cap is broken or missing.**

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)	
<b>USES:</b> Temporarily relieves minor aches and pains due to: ■ headache ■ a cold ■ arthritis ■ muscular aches ■ toothache ■ premenstrual & menstrual cramps	
<b>WARNINGS: REYE'S SYNDROME:</b> 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.	
<b>ALLERGY ALERT:</b> 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. <b>ALLERGY ALERT:</b> Aspirin may cause a severe allergic reaction which may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock.	
<b>LIVER WARNING:</b> 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.	
<b>STOMACH BLEEDING WARNING:</b> 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, etc.)	

Lot No. Exp. Dt.

**FL0112-00**



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Distributed by **GenCare Consumer Products, L.L.C.** 41E, Collins Ln, Suite A, East Brunswick, NJ 08816

(continued under label)

**Drug Facts** (continued)

naproxen, or others) ■ have 3 or more alcoholic drinks 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 heart beat.

**Do not use** ■ if you 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 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 for more than 10 days ■ fever gets worse or lasts 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 at 20 weeks or later in 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 (1-800-222-1222) 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 of age 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 between 20°-25°C (68°-77°F) ■ Close cap tightly after use ■ Read all product information before using. ■ Keep this box for important information.

**INACTIVE INGREDIENTS:** Colloidal Silicon Dioxide, Hypromellose, Microcrystalline Cellulose, Polyethylene Glycol, Pregelatinized Starch, Polyvinyl Pyrrolidone, Stearic Acid Powder, Talc.

**QUESTIONS OR COMMENTS?** Call 1-732-698-5070 Monday through Friday 9 AM to 5 PM EST.

†This product is not manufactured or distributed by GSK/Consumer Health, owner of the registered trademark EXCEDRIN® Extra Strength Tablets.

## GENCARE HEADACHE RELIEF

acetaminophen, aspirin, caffeine tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72090-007
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<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>	27mm
<b>Flavor</b>		<b>Imprint Code</b>	S53
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72090-007-02	300 in 1 BOTTLE; Type 0: Not a Combination Product	08/03/2020	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	08/03/2020	

**Labeler** - Pioneer Life Sciences, LLC (014092742)