

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

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 mgPain 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 gels 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	
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, etc.)	

(continued under label)

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

Lot No. Exp. Dt.

FL0112-00



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PEEL HERE

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

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	27mm
Flavor		Imprint Code	S53
Contains			

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)