

**EXTRA STRENGTH PAIN RELIEF- acetaminophen aspirin caffeine tablet,
coated
RITE AID**

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.

370R Riteaid 11822 7897 Acetaminophen, Aspirin & Caffeine Tablets

DRUG FACTS

Active ingredients (in each caplet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID)*

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever

Pain reliever

Pain reliever aid

Uses

temporarily relieves minor aches and pains due to:

- headache
- a cold
- arthritis
- muscular aches
- 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: 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
- 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 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

- 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

an allergic reaction occurs. Seek medical help right away.

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

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

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 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 20° - 25°C (68° - 77°F)
- close cap tightly after use

Inactive ingredients carnauba wax, colloidal silicon dioxide, hypromellose, microcrystalline cellulose, mineral oil, pregelatinized starch, povidone, sodium starch glycolate, stearic acid, titanium dioxide

Questions or comments?

Call 1-877-290-4008

RETAIN CARTON FOR COMPLETE PRODUCT INFORMATION

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 250 mg	Pain reliever
Aspirin (NSAID) 250 mg	Pain reliever
Caffeine 65 mg (NSAID)	Pain reliever and

Purpose

Nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to
- headache
- cold
- arthritis
- muscular aches
- toothache
- premenstrual and menstrual cramps

Warnings See carton for complete 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 redness
- blisters
- itching
- swelling
- skin peeling

Stop using this product and get medical help right away.

Allergy alert: Aspirin may cause a severe allergic reaction, which may include:

- hives
- facial swelling
- shock
- asthmalike 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 ulcers, bleeding, or other problems with your stomach or intestines in the past
- are taking aspirin, aspirin-containing products, or nonsteroidal NSAIDs (aspirin, ibuprofen, naproxen, or others)
- take 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.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during the last 6 months of pregnancy unless explicitly directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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

Other information

- DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING
- store at 20°-25°C (68°-77°F)
- close cap tightly after use

Questions or comments? Call 1-877-290-4008

DISTRIBUTED BY: RTE AID SATISFACTION GUARANTEE:
30 HUNTER LANE
CHAMP HILL, PA 17011
If you're not satisfied, we'll happily refund your money. 370R 0421

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

Lot No.:

Exp. Date:



EXTRA STRENGTH PAIN RELIEF

acetaminophen aspirin caffeine tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11822-7897
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MINERAL OIL (UNII: T5L8T28FGP)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE (Capsule shaped tablet)	Size	17mm
Flavor		Imprint Code	TCL370
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11822-7897-7	1 in 1 CARTON	05/31/2021	
1		200 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	05/31/2021	

Labeler - RITE AID (014578892)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
TIME CAP LABORATORIES, INC.		037052099	manufacture(11822-7897)