

**ACETAMINOPHEN, ASPIRIN, CAFFEINE- acetaminophen, aspirin,
caffeine tablet, film coated**
Rugby Laboratories

5004-Rugby

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 in a dry place at 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?

(800) 231-4670

RETAIN THIS CARTON FOR COMPLETE PRODUCT INFORMATION

DISTRIBUTED BY: RUGBY® LABORATORIES
INDIANAPOLIS, IN 46268
(800) 616-2471 www.majorpharmaceuticals.com

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

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

Rugby

Pain Reliever Plus

NDC 0536-1326-01

Compare to the active ingredients in Excedrin® Extra Strength Caplets†

Acetaminophen, Aspirin (NSAID)* and Caffeine

250mg/250mg/65mg

Pain Reliever/Pain Reliever Aid

NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN

100 Caplets

R52346

Rugby
Compare the active ingredients
in Excedrin® Extra Strength Caplets*

Pain Reliever Plus
Acetaminophen,
Aspirin (NSAID)*
and Caffeine
250 mg / 250 mg / 65 mg
Pain Reliever / Pain Reliever Aid

100 Caplets

Drug Facts (continued)

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

Drug Facts (continued)

■ 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 ■ pain gets worse or lasts for more than 10 days ■ fever gets worse or lasts for more than 3 days ■ redness or swelling is present ■ any new symptoms appear. These could be signs of a serious condition.

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

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NDC 0536-1326-01

Rugby
Compare the active ingredients
in Excedrin® Extra Strength Caplets*

Pain Reliever Plus
Acetaminophen, Aspirin (NSAID)* and Caffeine
250 mg / 250 mg / 65 mg
Pain Reliever / Pain Reliever Aid

100 Caplets

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Rev. 11/23 R-29 Re-order No. 302611



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ACETAMINOPHEN, ASPIRIN, CAFFEINE

acetaminophen, aspirin, caffeine tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0536-1326
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

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

Product Characteristics

Color	white	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	2793
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0536-1326-01	1 in 1 CARTON	06/03/2021	
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 Drug	M013	06/03/2021	

Labeler - Rugby Laboratories (079246066)

Revised: 5/2024

Rugby Laboratories