

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

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**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 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?***

1-800-645-2158

RETAIN THIS CARTON FOR COMPLETE PRODUCT INFORMATION

Distributed by: RUGBY® LABORATORIES, Livonia, MI 48152  
[www.rugbylaboratories.com](http://www.rugbylaboratories.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†

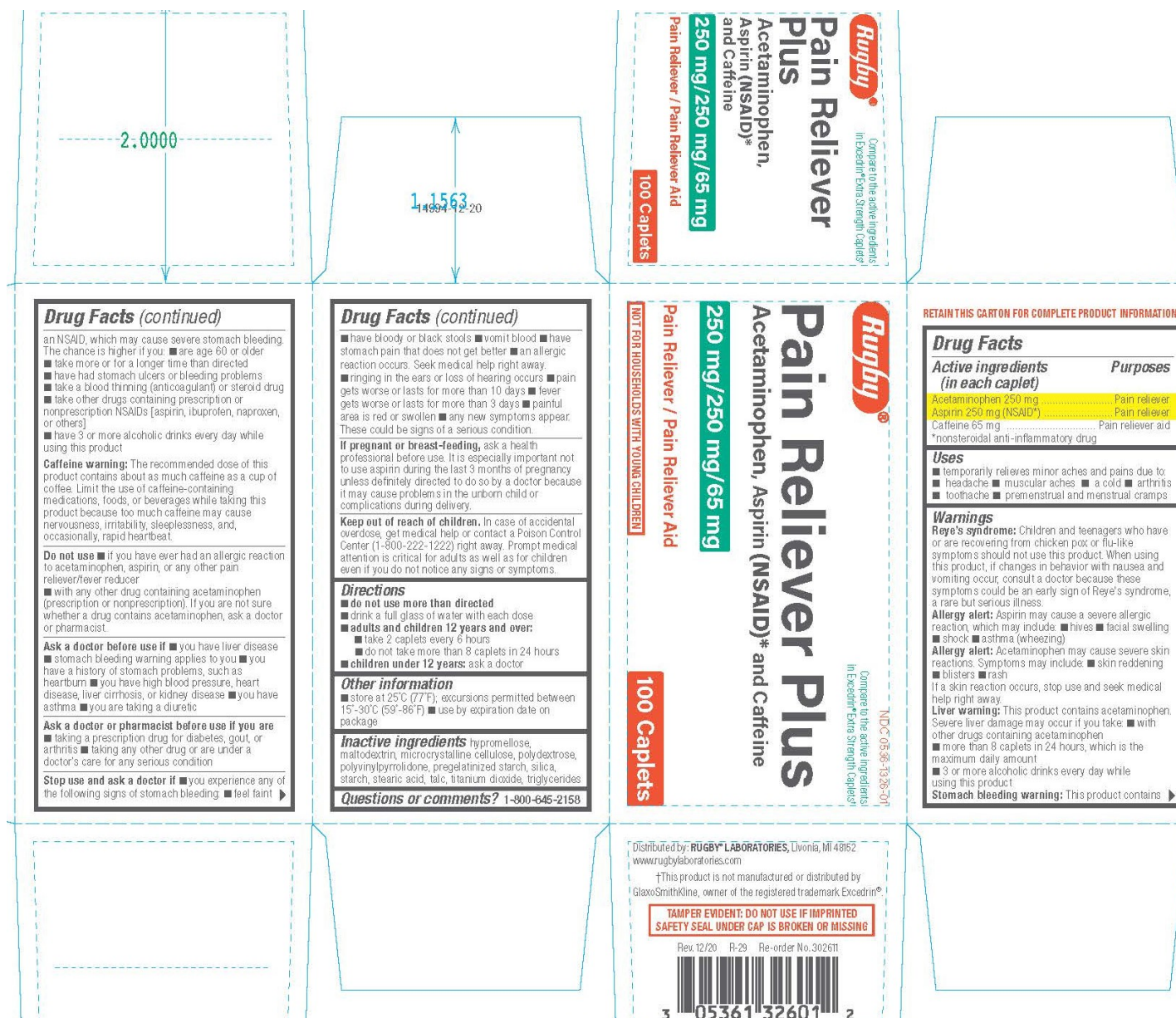
Acetaminophen, Aspirin (NSAID)\* and Caffeine

250mg/250mg/65mg

Pain Reliever/Pain Reliever Aid

NOT FOR HOUSEHOLDS WITH YOUNG CHILDREN

100 Caplets



## 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
<b>ASPIRIN</b> (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg

## Inactive Ingredients

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

## 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: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: 1/2024

Rugby Laboratories