

ACETAMINOPHEN, ASPIRIN AND CAFFEINE- acetaminophen, aspirin and caffeine tablet

Rising Pharma Holdings, Inc.

Compare to active ingredients in EXCEDRIN® EXTRA STRENGTH⁺

EXTRA STRENGTH

Acetaminophen, Aspirin (NSAID) and Caffeine

250 mg/250 mg/65 mg

Pain Reliever/ Pain Reliever Aid

100 Caplets

DO NOT USE IF PRINTED SEAL UNDER CAP IS MISSING OR DAMAGED

Drug Facts

Active ingredients (in each caplet)

Purposes

Acetaminophen USP, 250 mg.....Pain reliever

Aspirin USP, 250 mg (NSAID*).....Pain reliever

Caffeine USP, 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 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
- arthritis

- taking any other drug, or are under a doctor's care for any serious condition
- taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer.

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
 - vomit blood
 - have bloody or black stools
 - 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 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 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 right away (1-800-222-1222). 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 take 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)
- close cap tightly after use
- read all product information before using.

Inactive ingredients

Colloidal silicon dioxide , hypromellose, microcrystalline cellulose , polyethylene glycol, povidone, pregelatinized starch, stearic acid, talc

Questions and comments? Call 1-844-474-7464

Distributed by:

Rising Pharma Holdings, Inc.

East Brunswick, NJ 08816 Made in India Mfg. Lic. No.: G/25/1362

Issued: 09/2025

S-066

+This product is not manufactured or distributed by the owner of the registered trademark Excedrin[®] Extra Strength

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

**EXTRA STRENGTH Acetaminophen, Aspirin (NSAID) and Caffeine
250mg/250mg/65mg**

NDC 57237-348-01

100 Caplets



NDC 57237-348-01

Compare to active ingredients in EXCEDRIN® EXTRA STRENGTH*

EXTRA STRENGTH Acetaminophen, Aspirin (NSAID) and Caffeine

250 mg/250 mg/65 mg

Pain Reliever/ Pain Reliever Aid

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Drug Facts

Active ingredients (in each caplet)	Purposes
Acetaminophen USP, 250 mg	Pain reliever
Aspirin USP, 250 mg (NSAID)*	Pain reliever
Caffeine USP, 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 ■ menstrual & menstrual cramps

Warnings
Reyes 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 Reyes syndrome, a rare but serious illness.

Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin redness ■ 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 thinner (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.

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

Distributed by:
Rising Pharma Holdings, Inc.
East Brunswick, NJ 08816

Mfg. Lic. No.: G/2/5/1382
Issued: 09/20/25

S-086

OPEN FOR FULL LABELING

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Drug Facts (continued)

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 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 for plus/extra strength if you are ■ taking a prescription drug for ■ diabetes ■ gout ■ asthma ■ taking any other drug, or are under a doctor's care for any serious condition ■ taking any other product that contains aspirin, acetaminophen, or any other pain reliever/fever reducer.

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: ■ live spit ■ vomit blood ■ have bloody or black stools ■ have stomach pain that does not get better ■ ringing in the ears or loss of hearing occurs ■ stools get 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.

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use aspirin during 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 right away (1-800-222-1222). Promot medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions
■ do not take 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)
■ close cap tightly after use
■ read all product information before using.

Inactive ingredients
Colloidal silicon dioxide, hydroxyethylcellulose, microcrystalline cellulose, polyethylene glycol, polydioxane, polydimethylsiloxane, stearic acid, talc.

Questions and comments? Call 1-844-47-4664

ACETAMINOPHEN, ASPIRIN AND CAFFEINE

acetaminophen, aspirin and caffeine tablet

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57237-348
Route of Administration	ORAL		

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white (Off White)	Score	no score
Shape	ROUND	Size	11mm
Flavor		Imprint Code	S7
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57237-348-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/09/2025	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	07/09/2025	

Labeler - Rising Pharma Holdings, Inc. (116880195)

Registrant - Elysium Pharmaceuticals Ltd (915664486)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		863182240	label(57237-348) , pack(57237-348)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceuticals Ltd		915664486	manufacture(57237-348) , analysis(57237-348)

