

**DR SIMI EXTRA STRENGTH ACETAMINOPHEN 250 MG, ASPIRIN 250 MG, AND
CAFFEINE 65 MG- acetaminophen 250 mg, aspirin 250 mg, and caffeine 65
mg tablet, coated**
Farmacias De Similares TX LLC

Active Ingredients (in each caplet)

Acetaminophen 250 mg

Aspirin 250 mg (NSAID*)

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

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

- muscular aches

- a cold

- arthritis

- 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: 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

- 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
- 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

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

Inactive ingredients

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

Questions or comments?

855-280-1079

t This product is not manufactured or distributed by Haleon, owner of the registered trademark Excedrin®.

Distributed by:

FARMACIAS DE SIMILARES TX LLC

800 Brazos St Ste 260, Austin, TX, 78701, USA

customerservice@drsimi.com

www.drsimi.com

Drug Facts (continued)

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

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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

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Drug Facts (continued)

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DR. SIMI

NDC: 85786-105-90

Compare to Excedrin® Extra Strength Headache Relief Active ingredients |

Extra Strength

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

Pain Reliever / Pain Reliever Aid

100 Caplets

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

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Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include: ■ skin reddening ■ blisters ■ rash

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Stomach bleeding warning: This product contains an NSAID, which may cause severe stomach bleeding. ▶

Dr. Simi

NDC: 85786-105-90

Compare to Excedrin® Extra Strength Headache Relief Active ingredients t

Extra Strength Acetaminophen 250 mg, Aspirin 250 mg (NSAID)* and Caffeine 65 mg

Pain Reliever / Pain Reliever Aid

100 Caplets

DR SIMI EXTRA STRENGTH ACETAMINOPHEN 250 MG, ASPIRIN 250 MG, AND CAFFEINE 65 MG			
acetaminophen 250 mg, aspirin 250 mg, and caffeine 65 mg tablet, coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:85786-105
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) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	250 mg	
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg	
Inactive Ingredients			
Ingredient Name	Strength		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)			

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

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:85786-105-90	100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	01/01/2026	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/01/2026	

Labeler - Farmacias De Similares TX LLC (119489934)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp		057795122	pack(85786-105) , label(85786-105)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp		079157508	manufacture(85786-105)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp		968334974	manufacture(85786-105)

Establishment

Name	Address	ID/FEI	Business Operations
Contract Pharmacal Corp		968335112	manufacture(85786-105)

Revised: 1/2026

Farmacias De Similares TX LLC