

SEDALMEX FORTE- acetaminophen, aspirin, caffeine tablet
Belmora LLC

SEDALMEX FORTE

Drug Facts

Active ingredients (in each tablet)

Acetaminophen 250 mg

Aspirin (NSAID*) 250 mg

Caffeine 65 mg

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/fever reducer

Pain reliever/fever reducer

Pain reliever aid

Uses

temporarily relieves minor aches and pains due to:

- headache • muscular aches • arthritis pain
- a cold • 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 (NSAIDs) 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 tablets 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)
- take more or for a longer time than directed
- 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 heart beat.

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.
- If you ever have had an allergic reaction to acetaminophen, aspirin or any other pain relievers/fever reducers

Ask a doctor before use if

- stomach bleeding warning applies to you
- you have high blood pressure, heart disease, liver cirrhosis, or kidney disease
- you are taking a diuretic • you have a history of stomach problems, such as heartburn
- you have asthma • you have liver disease

Ask a doctor or pharmacist before use if you are

- if you are taking prescription drug for gout, diabetes, or arthritis
- taking any other drug, or 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 • vomit blood • have bloody or black stools
 - have stomach pain that does not get better
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- ringing in the ears or loss of hearing occurs
- painful area is red or swollen
- any new symptoms occur

These could be signs of a serious condition.

If pregnant or breast-feeding, ask a health care professional before use. It is especially important not to use aspirin at 20 weeks or later in 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. 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 older)	Take 2 Tablets every 6 hours as needed; not more than 8 tablets in 24 hours
Children under 12 years:	Ask a doctor

Other information

- read all product information before using. Keep box for important information.
- store at room temperature between 68°-77°F (20°-25°C)
- avoid excessive heat and humidity
- tamper evident sealed packets
- do not use any opened or torn packets
- **each tablet contains: Magnesium 0.58 mg**

Inactive ingredients

colloidal silicon dioxide, hypromellose, microcrystalline cellulose, polyvinyl pyrrolidone, polyethylene glycol, pregelatinized starch, starch 1500, stearic acid, talc

Questions or comments?

1-888-779-2877 M-F 9AM-5PM EST

Fast Headache Relief!

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

Distributed by


Belmora LLC, 3033 Wilson BLvd.,

Suite 700. Arlington, VA 22201,

MADE IN INDIA

Packaging

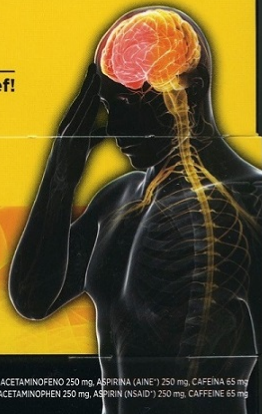
NDC 27854-303-01



SEDALMEX FORTE

Acetaminofeno, Aspirina & Cafeína Ayuda para el alivio del dolor. / Acetaminophen, Aspirin & Caffeine Pain reliever.

¡Alivio Rápido del Dolor de Cabeza!
Fast Headache Relief!



ALIVIO TEMPORAL DE DOLORES Y MOLESTIAS MENORES.
TEMPORARY RELIEF OF MINOR ACHEs & PAINS.

20 DUAL PACKETS/PAQUETES DUALES
1 TABLET PER PACKET/TABLETA POR PAQUETE
40 TABLET/TABLETAS

ACETAMINOFENO 250 mg, ASPIRINA (AINS*) 250 mg, CAFEINA 65 mg
ACETAMINOPHEN 250 mg, ASPIRIN (NSAID)* 250 mg, CAFFEINE 65 mg

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Drug Facts (continued)

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Distributed by/Distribuido por:
**Belmora LLC, 3033 Wilson Blvd.,
Suite 700, Arlington, VA 22201**

MADE IN INDIA/
HECHO EN INDIA

SEDALMEX FORTE

acetaminophen, aspirin, caffeine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:27854-303
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE K30 (UNII: U725QWY32X)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ05DW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white (WHITE TO OFF WHITE WTH SPECKS)	Score	no score
Shape	capsule (CAPSULE SHAPED BICONVEX)	Size	18mm
Flavor		Imprint Code	S53
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-303-01	40 in 1 BOX	06/01/2024	
1		1 in 1 PACKET; 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	06/01/2024	

