

**SEDALMEX- acetaminophen, caffeine tablet, coated**  
**Belmora LLC**

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**Sedalmex 44-572**

***Active ingredients (in each gelcap)***

Acetaminophen 500 mg  
(formulated with 65 mg caffeine)

***Purpose***

Pain reliever

***Uses***

- temporarily relieves minor aches and pains due to:
  - headache
  - muscular aches

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**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.

**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 are allergic to acetaminophen

**Ask a doctor before use if you have**

liver disease.

**Ask a doctor or pharmacist before use if you are**

taking the blood thinning drug warfarin.

**Stop use and ask a doctor if**

- new symptoms occur
- painful area is red or swollen
- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days

These could be signs of a serious condition.

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of reach of children.**

In case of accidental overdose, get medical help or contact a Poison Control Center 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 take more than directed**
- adults and children 12 years and over: take 2 gelcaps every 6 hours. Do not take more than 6 gelcaps in 24 hours.
- children under 12 years: ask a doctor

***Other information***

- store at 25°C (77°F); excursions permitted between 15°C-30°C (59°F-86°F)
- avoid high humidity
- see end flap for expiration date and lot number

***Inactive ingredients***

corn starch, FD&C blue #1, FD&C red #40, gelatin, hydroxypropyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, propylene glycol, shellac glaze, silicon dioxide, simethicone, sodium starch glycolate, stearic acid, titanium dioxide

***Questions or comments?***

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

***Principal display panel***

NDC 27854-301-01

**SEDALMEX**

**RAPID RELEASE**

Temporary relief of minor aches & pains.

**Acetaminophen &  
Caffeine Pain Reliever**

**24 GELCAPS**

Actual Size

ACETAMINOPHEN 500 mg, CAFFEINE 65 mg

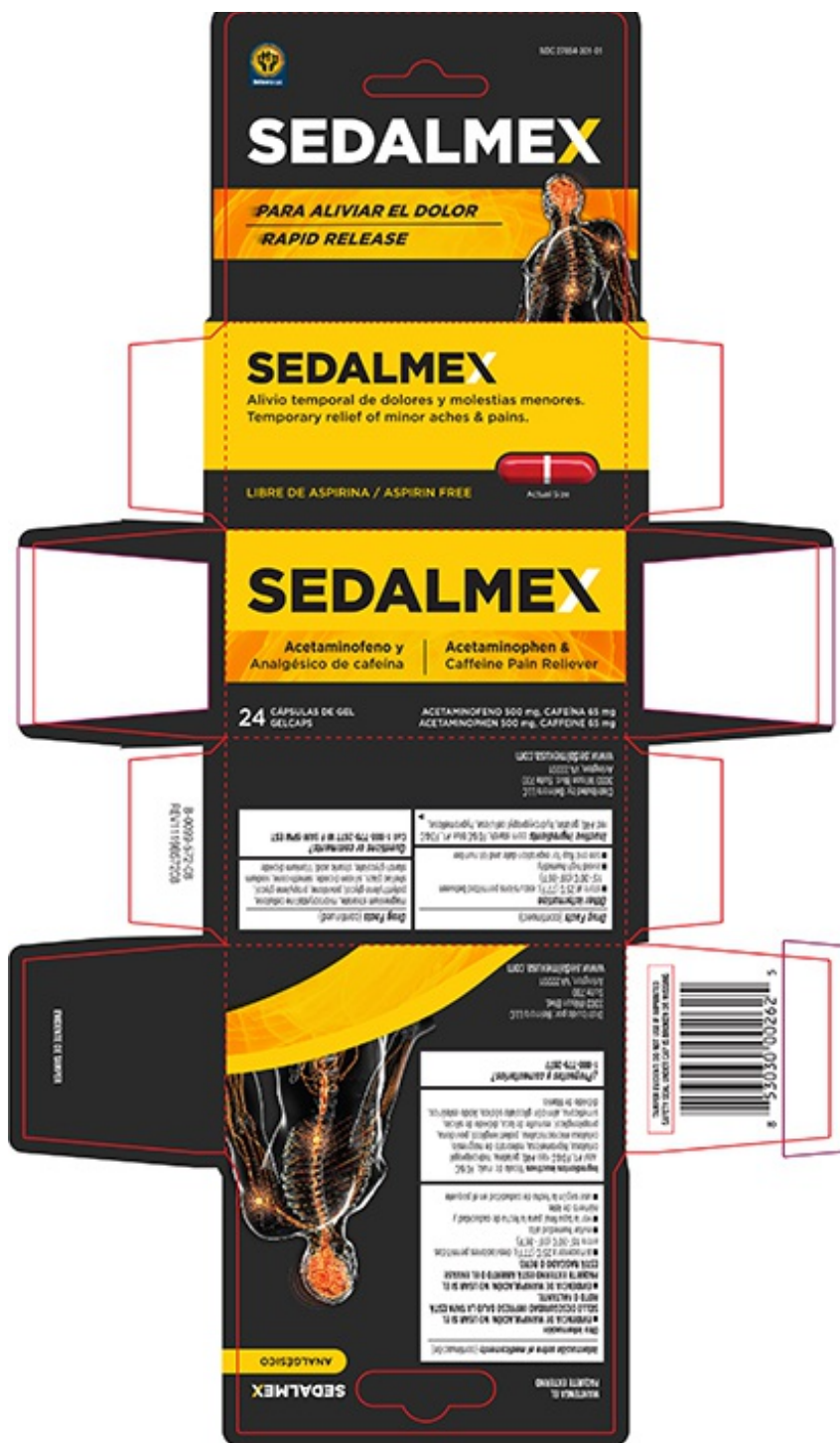
ASPIRIN FREE

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

Distributed by: Belmora LLC  
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Arlington, VA 22201  
www.sedalmexusa.com

REV1119B57208





**Sedalmex B-0099-572-08 REV1119B**

## SEDALMEX

acetaminophen, caffeine tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:27854-301
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	65 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	red	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	20mm
<b>Flavor</b>		<b>Imprint Code</b>	L;2
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:27854-301-01	1 in 1 CARTON	08/08/2019	
1		24 in 1 BOTTLE, PLASTIC; 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	08/08/2019	

**Labeler** - Belmora LLC (112753244)

