

GEMMA CUT THE CRAMP- aspirin, caffeine tablet, effervescent Rally Labs LLC

Active ingredients (in each tablet)	Purpose
Aspirin 500 mg (NSAID*).....	Pain reliever
Caffeine 60 mg.....	Pain reliever aid / Alertness aid

*Nonsteroidal anti-inflammatory drug

Uses

Uses

- For the temporary relief of these symptoms associated with menstrual periods:
- cramps • fatigue • backache • headache • bloating • muscle aches

Warnings

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 • asthma (wheezing) • shock

Stomach bleeding warning: This product contains a nonsteroidal anti-inflammatory drug (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 non-prescription 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 because too much caffeine may cause nervousness, irritability, sleeplessness, and occasionally, rapid heart beat. For occasional use only.

Do not use if you have ever had an allergic reaction to aspirin or any other pain reliever/fever reducer

Ask A Doctor Before Use

Ask a doctor before use if • 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 • you have a sodium-restricted diet

Ask a doctor or pharmacist before use if you are taking a prescription drug for • diabetes • gout • arthritis

Stop Use

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 lasts for more than 10 days or gets worse • new symptoms occur • redness or swelling is present • ringing in the ears or a loss of hearing occurs.

If Pregnant or Breastfeeding

If pregnant or breastfeeding, 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 overdose, get medical help or contact a Poison Control Center right away.

Directions

Directions

Directions: Fully dissolve 1 or 2 tablets in 16 oz. of water and drink.

- Adults and children 12 years and older: 1 or 2 tablets every 6 hours as needed. Do not exceed 8 tablets in 24 hours.
- Children under 12 years: do not use

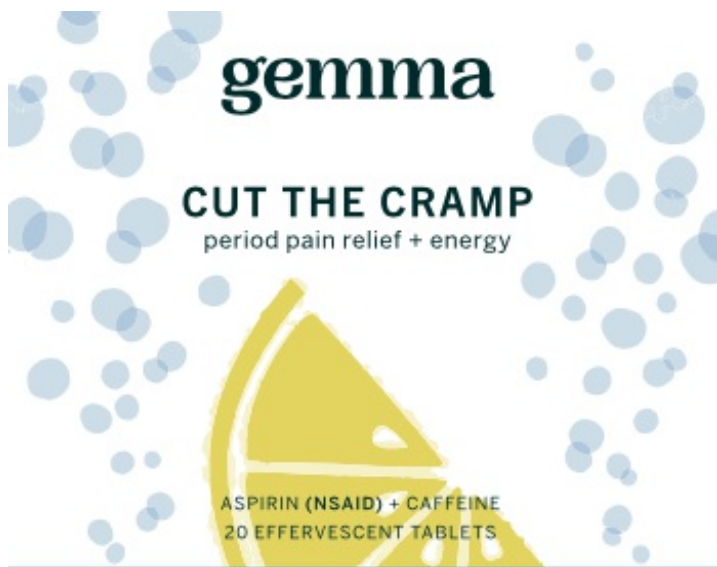
Inactive Ingredients

Inactive Ingredients acesulfame potassium, anhydrous citric acid, aspartame, docusate sodium, flavors, mannitol, povidone, sodium benzoate, sodium bicarbonate

Purpose

Active ingredients (in each tablet)

Aspirin 500 mg (NSAID*).....Pain reliever
 Caffeine 60 mg.....Pain reliever aid / Alertness aid
 *Nonsteroidal anti-inflammatory drug

Purpose**GEMMA CUT THE CRAMP**

aspirin, caffeine tablet, effervescent

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:75920-0465
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ASPIRIN (UNII: R16CO5Y76E) (ASPIRIN - UNII:R16CO5Y76E)	ASPIRIN	500 mg in 1000 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	60 mg in 1000 mg

Inactive Ingredients

Ingredient Name	Strength
SODIUM BICARBONATE (UNII: 8MDF5V39QO)	

Product Characteristics

Color	white	Score	score with uneven pieces
Shape	ROUND	Size	26mm
Flavor	LEMON	Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:75920-0465-2	20 in 1 CARTON	04/23/2024	
1		6816 mg in 1 POUCH; 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	04/23/2024	

Labeler - Rally Labs LLC (965453108)

Revised: 4/2024

Rally Labs LLC