

MEDIQUE PAIN OFF- acetaminophen, aspirin, caffeine tablet, film coated
Unifirst First Aid Corporation

Medique Pain-Off

Drug Facts

Active ingredients (in each caplet)

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 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)
- 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

- taking a 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 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 at 20 weeks or later in pregnancy unless specifically 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 over) Take 2 caplets every 6 hours as needed; not more than 8 caplets 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 68°-77°F (20°-25°C)

- avoid excessive heat and humidity

- tamper evident sealed packets

- do not use any opened or torn packets

- **each caplet 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? 1-800-634-7680

Medique®

Pain-Off®

Extra Strength Pain Relief

Alivio al dolor extra fuerte

Pain Reliever/Fever Reducer • Acetaminophen 250 mg Aspirin (NSAID) 250 mg

Alivia el Dolor/Reduce la Fiebre • Acetaminofeno 250 mg Aspirina (AINE) 250 mg

Pain Reliever Aid • Caffeine 65 mg
 Ayuda al alivio del dolor • Cafina 65 mg
 Pull to Open
 Tire Para Abrir
 200 Caplets (100 x 2)
 Tamper Evident Unit Dose Packets
 Empaquetado con Sellado Evidente en Dosis Unitarias

Medique Pain-Off
 Extra Strength Pain Relief
 Alivio de dolor extra fuerte

✓ Pain Reliever/Fever Reducer • Acetaminophen 250 mg Aspirin (NSAID) 250 mg
 ✓ Pain Reliever Aid • Caffeine 65 mg
 Ayuda al alivio del dolor • Cafina 65 mg

Drug Facts
 Active ingredients (in each caplet): Acetaminophen 250 mg, Aspirin (NSAID) 250 mg, Caffeine 65 mg.
 Use: Take as directed. Do not take more than 2 tablets in 24 hours.
 Warnings: Do not take if you are allergic to aspirin or have a history of stomach ulcers.
 Directions: Take 1 or 2 tablets every 4 to 6 hours as needed, not more than 2 tablets in 24 hours.

Información del medicamento
 Ingredientes activos (en cada comprimido): Acetaminofeno 250 mg, Aspirina (NSAID) 250 mg, Cafeína 65 mg.
 Uso: Tome como se indica. No tome más de 2 comprimidos en 24 horas.
 Advertencias: No tome si es alérgico a la aspirina o si tiene antecedentes de úlceras estomacales.
 Indicaciones: Tome 1 o 2 comprimidos cada 4 a 6 horas según sea necesario, no más de 2 comprimidos en 24 horas.

200 Caplets (100 x 2)
 Tamper Evident Unit Dose Packets
 Empaquetado con Sellado Evidente en Dosis Unitarias

MEDIQUE PAIN OFF

acetaminophen, aspirin, caffeine tablet, film coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47682-238
Route of Administration	ORAL		

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

Inactive Ingredients	
Ingredient Name	Strength

TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	

Product Characteristics

Color	white ((white to off white with 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:47682-238-13	250 in 1 BOX	06/01/2021	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:47682-238-33	50 in 1 BOX	06/01/2021	
2		2 in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:47682-238-99	2 in 1 PACKET; Type 0: Not a Combination Product	06/01/2021	
4	NDC:47682-238-47	100 in 1 BOX	06/01/2021	
4		2 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	06/01/2021	

Labeler - Unifirst First Aid Corporation (832947092)