

MEDI FIRST PMS RELIEF- acetaminophen, pamabrom, pyrilamine maleate tablet, coated

MEDI FIRST PLUS PMS RELIEF- acetaminophen, pamabrom, pyrilamine maleate tablet, coated

Unifirst First Aid Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Medi-First/Medi-First Plus PMS Relief

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 500 mg

Pamabrom 25 mg

Pyrilamine maleate 15 mg

Purpose

Pain reliever

Diuretic

Antihistamine

Uses

for the temporary relief of these symptoms associated with menstrual periods:

- headache
- bloating
- cramps
- backache
- muscular aches
- irritability
- water-weight gain

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.

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 have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- difficulty in urination due to enlargement of the prostate gland
- a breathing problem such as emphysema or chronic bronchitis
- liver disease
- glaucoma

Ask a doctor or pharmacist before use if you are

- taking sedatives or tranquilizers
- taking the blood thinning drug warfarin

When using this product

- drowsiness may occur
- avoid alcoholic beverages
- excitability may occur, especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness
- use caution when driving a motor vehicle or operating machinery

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

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 (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 take more than directed

Adults and children: (12 years and over)

- take 2 caplets with water every 6 hours as needed
- do not exceed 6 caplets in a 24 hour period or as directed by a doctor

Children under 12 years: ask a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
- tamper-evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

corn starch, croscarmellose sodium, crospovidone, FD&C blue #2 aluminum lake, FD&C red #40 aluminum lake, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, shellac wax, silicon dioxide, stearic acid, talc, titanium dioxide

Questions or comments? 1-800-634-7680

Medi-First®

PMS Relief

Pain Reliever • Acetaminophen 500 mg

Diuretic • Pamabrom 25 mg

Antihistamine • Pyrilamine maleate 15 mg

Menstrual Pain Relief

Pull to Open

This Package is for Households Without Young Children.

Tamper Evident Unit Dose Packets

80 Caplets

(40 x 2)



Medi-First® Plus
PMS Relief
Pain Reliever • Acetaminophen 500 mg
Diuretic • Pamabrom 25 mg
Antihistamine • Pyrilamine maleate 15 mg
This Package is for Households Without Young Children.
Pull to Open
Relief from Menstrual Pain, Water Retention and Bloating
Tamper Evident Unit Dose Packets
80 Caplets
(40 x 2's)



MEDI FIRST PMS RELIEF

acetaminophen, pamabrom, pyrilamine maleate tablet, coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:47682-823
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PAMABROM (UNII: UA8U0KJM72) (BROMOTHEOPHYLLINE - UNII:FZ G87K1MQ6)	PAMABROM	25 mg
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	15 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2--ALUMINUM LAKE (UNII: 4AQJ3LG584)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
TALC (UNII: 7SEV7J4R1U)	
CROSPVIDONE (UNII: 2S7830E561)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SHELLAC (UNII: 46N107B71O)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	purple	Score	no score
Shape	CAPSULE (Caplet)	Size	17mm
Flavor		Imprint Code	44;679
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:47682-823-80	40 in 1 BOX	09/26/2022	
2	NDC:47682-823-	2 in 1 PACKET; Type 0: Not a Combination		

1	99	Product		
2	NDC:47682-823-36	75 in 1 BOX	02/01/2023	
2	NDC:47682-823-99	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 not final	part343	09/26/2022	

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TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
TALC (UNII: 7SEV7J4R1U)	
CROSPVIDONE (UNII: 2S7830E561)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SHELLAC (UNII: 46N107B710)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
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Labeler - Unifirst First Aid Corporation (832947092)

Revised: 3/2023

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