

FEM-PRIN- acetaminophen, pamabrom, pyrilamine maleate tablet, film coated HART Health

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.

FEM-PRIN

Active ingredient (in each caplet)

Acetaminophen 500 mg

Pamabrom 25 mg

Pyrilamine maleate 15 mg

Purpose

Pain reliever/fever reducer

Diuretic

Antihistamine

Uses

for the temporary relief of minor aches, pain, and water weight gain due to menstrual cycle

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

Do not use

- with any other drug containing acetaminophen (prescription or nonprescription).

Ask a doctor before use if you have

- a breathing problem such as emphysema or chronic bronchitis
- trouble urinating due to an enlarged prostate gland
- liver disease

- glaucoma

Ask a doctor or pharmacist before use if

- you do not know if other drugs you are taking contain acetaminophen
- you are taking sedatives or tranquilizers
- you are taking the blood thinning drug warfarin

When using this product

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

Stop use and ask a doctor if

- an allergic reaction occurs, seek medical help right away
- fever worsens or lasts more than 3 days
- pain worsens or lasts more than 10 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.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. Quick medical attention is critical for adults as well as for children even if you do notice any signs or symptoms. In case of overdose, get medical help or contact a Poison Control Center right away. 1-800-222-1222

Directions

Do not take more than directed

Adults and children 12 years of age and over

- take 2 caplets every 6 hours while symptoms persist
- do not take more than 6 caplets in 24 hours unless directed by a doctor

Children under 12 years: ask a doctor

Other information

- caplets enclosed in a sealed packet

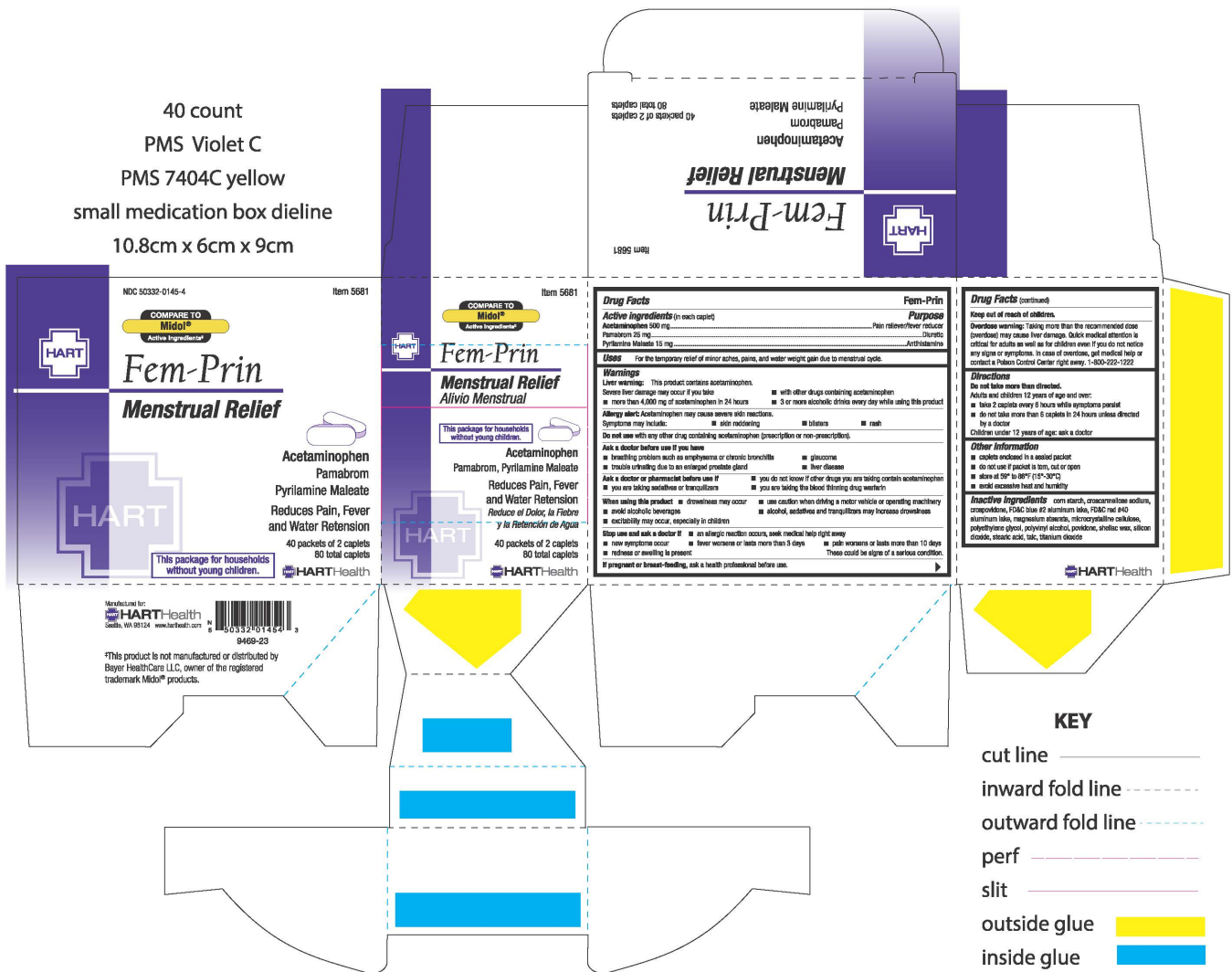
■ do not use if packet is torn, cut or open

■ store at 59° to 86°F (15°-30°C)

■ avoid excessive heat and humidity

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



FEM-PRIN			
acetaminophen, pamabrom, pyrilamine maleate tablet, film coated			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:50332-0145
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PAMABROM (UNII: UA8U0KJM72) (BROMOTHEOPHYLLINE - UNII:FZG87K1MQ6)	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)	
CROSCARMELLOSE 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: 46N107B710)	
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:50332-0145-4	40 in 1 BOX	01/09/2023	
1		2 in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:50332-0145-7	100 in 1 BOX	01/09/2023	
2		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		01/09/2023	

final

part 43

01/09/2023

Labeler - HART Health (069560969)

Revised: 8/2023

HART Health