

# **FEM-PRIN- acetaminophen, pamabrom, pyrilamine maleate tablet, film coated**

## **HART Health**

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### **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

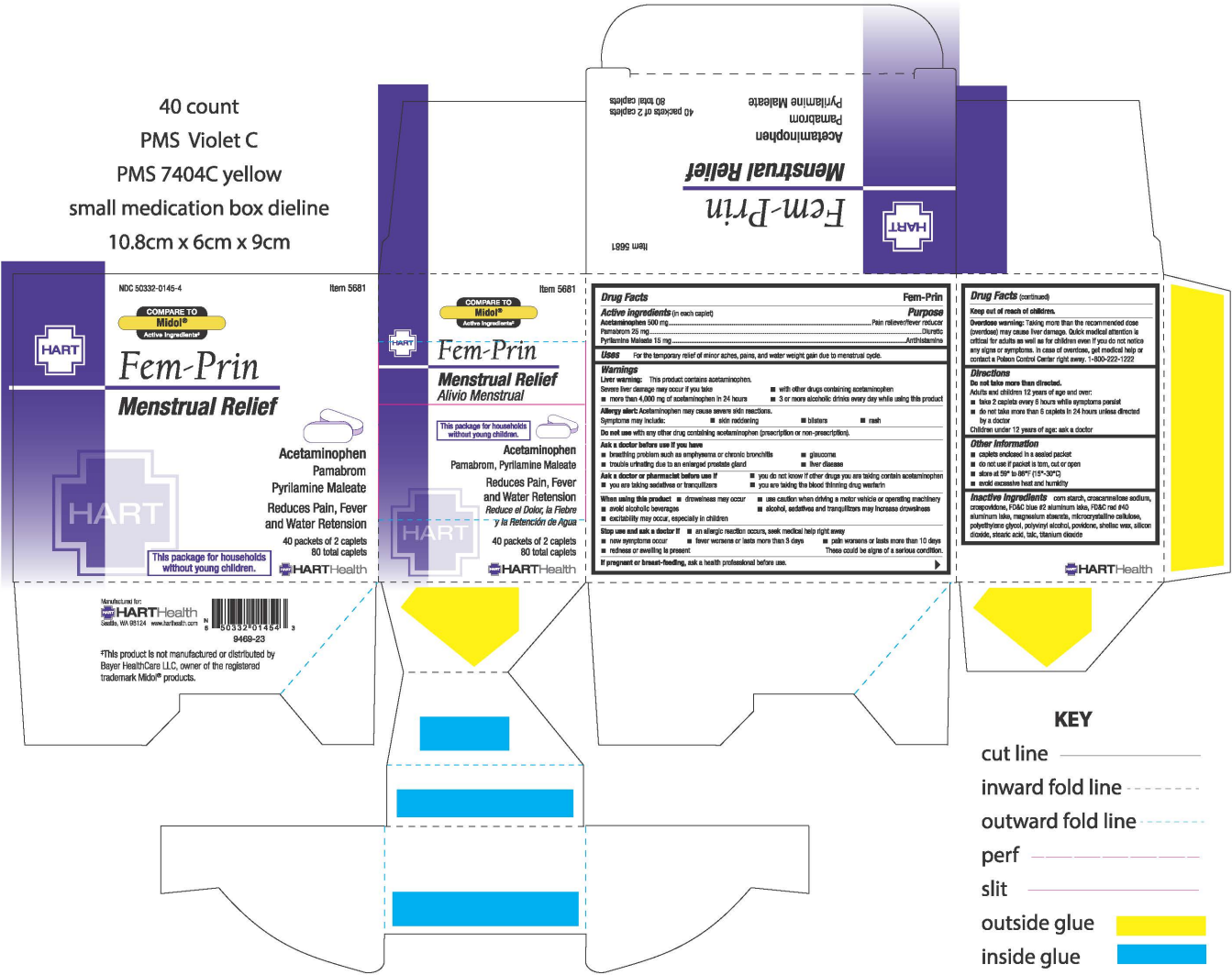
#### ***Other information:***

- 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

<b>PYRILAMINE MALEATE</b> (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	15 mg
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

### Inactive Ingredients

Ingredient Name	Strength
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 2--ALUMINUM LAKE</b> (UNII: 4AQJ3LG584)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>CROSPVIDONE</b> (UNII: 2S7830E561)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

### Product Characteristics

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

### 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 Drug	M	01/09/2023	

