

PREMSYN PMS PREMENSTRUAL PAIN RELIEF- acetaminophen and pamabrom and pyrilamine maleate tablet
Focus Consumer Healthcare, LLC

Premsyn pms Premenstrual Pain Relief

(in each caplet)

Acetaminophen 500 mg

Pamabrom 25 mg

Pyrilamine maleate 15 mg

Pain reliever

Antihistamine

Diuretic

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

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

Allergy Warning: 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.

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

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.

Ask a doctor before use if you have:

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

Ask a doctor or pharmacist before use if you are:

- taking the blood thinning drug warfarin
- taking sedatives or tranquilizers
- When using this product,
- you may get drowsy, avoid alcoholic beverages
- alcohol, sedatives and tranquilizers may increase drowsiness
- use caution when driving or operating machinery
- excitability may occur, especially in children

stop use and ask doctor if:

- Pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days
- new symptoms occur
- redness or swelling is present
- If pregnant or breastfeeding, ask a health professional before use.

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.

Ask a doctor before use if

you have

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

Ask a doctor or pharmacist before use

if you are

- taking the blood thinning drug warfarin
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When using this product

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

Stop use and ask a doctor if

- pain gets worse or lasts for more than 10 days
- fever gets worse or lasts for more than 3 days

- new symptoms occur
- redness or swelling is present

If pregnant or breast-feeding,

ask a health professional before use.

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.

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.

adults and children 12 years and over:

- take 2 caplets with water every 6 hours as needed
- do not exceed 8 caplets in a 24 hour period or as directed by a doctor
- do not use more than directed (see warnings)

children under 12 years: ask a doctor

blue 2, candelilla wax, corn starch, ethylparaben, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylparaben, red 40, sodium starch glycolate, stearic acid, talc, titanium dioxide

FOCUS CONSUMER HEALTHCARE

BRAND: Premysyn WORK ORDER # x

INFORMATION	PRODUCTION	COLORS	DATE CREATED
PROJECT NAME PREM 40CT CTN FILE NAME PREM 40CT CTN 004492902.PCH.A PART NO. 004492902 UFC NO. 371687 31024 0 ACCOUNT BRITTANY DEEMAN 642.814.8116 DESIGNER ANGIE JORDAN 423.227.4159 PRODUCTION OTHER INFO -	PROGRAM ILLUSTRATOR CC DIE LINE # CH-2867 POINTS OUTLINED PRINT METHOD OFFSET/FLEXO STOCK 16pt SBS PRINTER TPC COATING DUV GLOSS U AQUEOUS DUV MATTE U GLOSS VAB OTHER	4 COLOR Note: All colors for reference only, printed to use pre-approved color/delta/delta when printing. 	REVISIONS V2 10.03.17 V3 V4 V5 V6 V7

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Drug Facts (continued)

When using this product

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

Stop use and ask a doctor if

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

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

Drug Facts (continued)

Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions adults and children 12 years and over:

- Take 2 caplets with water every 6 hours as needed.
- Do not exceed 8 caplets in a 24 hour period or as directed by a doctor
- Do not use more than directed (see warnings)

children under 12 years: ask a doctor

Inactive ingredients

blue 2, candelilla wax, corn starch, ethylparaben, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, propylparaben, red 40, sodium starch glycolate, stearic acid, talc, titanium dioxide (E-141)



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Chattanooga, TN 37402 USA
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IFC PROOF Date: _____

OFC Item #: 5141/40CC
 Product ID: 11999
 Deline #: 28267

CPG

Print: Letter 8 1/2 x 11 11 x 17
 Varnish: Agross (gross) Net (net)

PT Board: 016 86

GRAPHIC DEPT. CHECK OK

Type Size (± 5 point)
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Unvarnished Area (lot/exp) ≥ 0.50" x 0.95"

Color Swatches and Label Color Match

UPC Scans Meets 80% size requirement

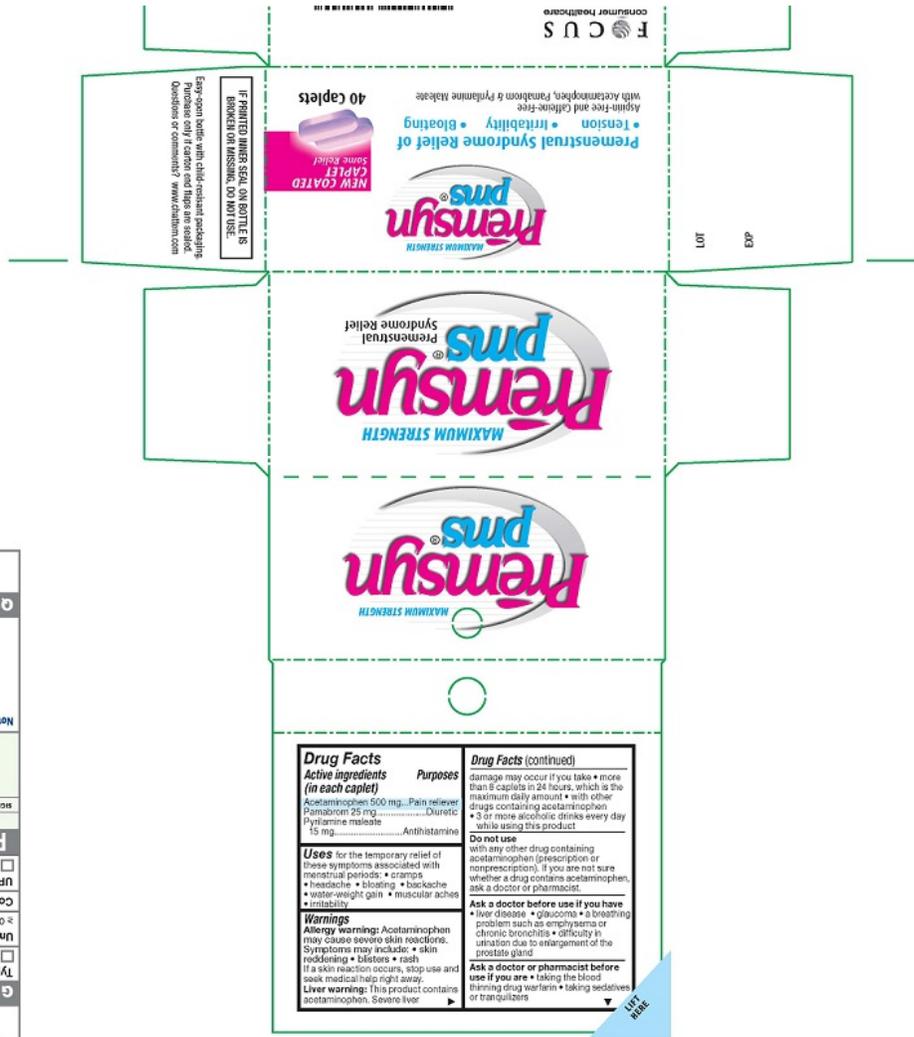
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Note:

QUESTIONS OR COMMENTS: _____

artdept@cpcc.com



PREMSYN PMS PREMENSTRUAL PAIN RELIEF

acetaminophen and pamabrom and pyrilamine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:71687-3102
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
PAMABROM (UNII: UA8U0KJM72) (BROMOTHEOPHYLLINE - UNII:FZG87K1MQ6)	PAMABROM	25 mg
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	15 mg

Inactive Ingredients

Ingredient Name	Strength
CROSPVIDONE (UNII: 68401960MK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POVIDONE (UNII: FZ989GH94E)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
STARCH, CORN (UNII: O8232NY3SJ)	

Product Characteristics

Color	purple (FD & C Red No. 40)	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	P
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71687-3102-4	1 in 1 CARTON	10/13/2017	
1		40 in 1 BOTTLE, PLASTIC; 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	10/13/2017	

Labeler - Focus Consumer Healthcare, LLC (080743737)

Revised: 4/2025

Focus Consumer Healthcare, LLC