

PREMSYN PMS PREMENSTRUAL PAIN RELIEF- acetaminophen and pamabrom and pyrilamine maleate tablet

Focus Consumer Healthcare, LLC

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.

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
- 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 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.

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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, candellilla 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 | | FOCUS CONSUMER HEALTHCARE ARTWORK | |
|---|--|---|--|
| INFORMATION PROJECT NAME: PREM 40CT CTN FILE NAME: PREM 40CT CTN 00449292.PCH.M PART NO.: 00449292 UPC NO.: 3 71687 31024 0 ACCOUNT: BRITTANY DEMANN 662.816.8116 DESIGNER: ANGIE JOBDAN 423.227.4159 PRODUCTION: | | PRODUCTION PROGRAM: ILLUSTRATOR CC DIE LINE #: CH-2847 PRINT METHOD: OFFSET/FLEXO STOCK: 14pt SBS PRINTER: TFC COATING: DUV MATE U GLOSS V48 OTHER: | |
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| DATE CREATED 9.14.17 | | WORK ORDER #: x | |



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
- dizziness or lightheadedness 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, candellilla 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 (449-609-055)

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www.premhm.com
Pain Relief
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Chattanooga, TN 37424 USA
801 Broad Street
Pain Relief
FOCUS
Consumer Healthcare

40 Caplets

NEW COATED CAPLET

Some pain relief with a different packaging. Please visit www.premhm.com for more information and to learn more about our products and services.

Premsym
MAGNESIUM STEARATE

Aspirin-Free and Caffeine-Free

• Tension • Irritability • Bloating

with acetaminophen, Paracetamol & Pyriminone Mixture





artdept@cpc.com

QUESTIONS OR COMMENTS:

Note:

| | | | |
|----------|----------|----------|----------|
| SCANNERS | SCANNERS | SCANNERS | SCANNERS |
|----------|----------|----------|----------|

APPROVED CHANGES

PROOFING STATUS

Meets 80% size requirement

UPC Scans

Color Swatches and Label Color Match

Unvarnished Area (lot/exp) 8.00" x 0.95"

Type in office, can't verify

GRAPHIC DEPT. CHECK OK

Type Size (2 point)

PT Board: 016 306

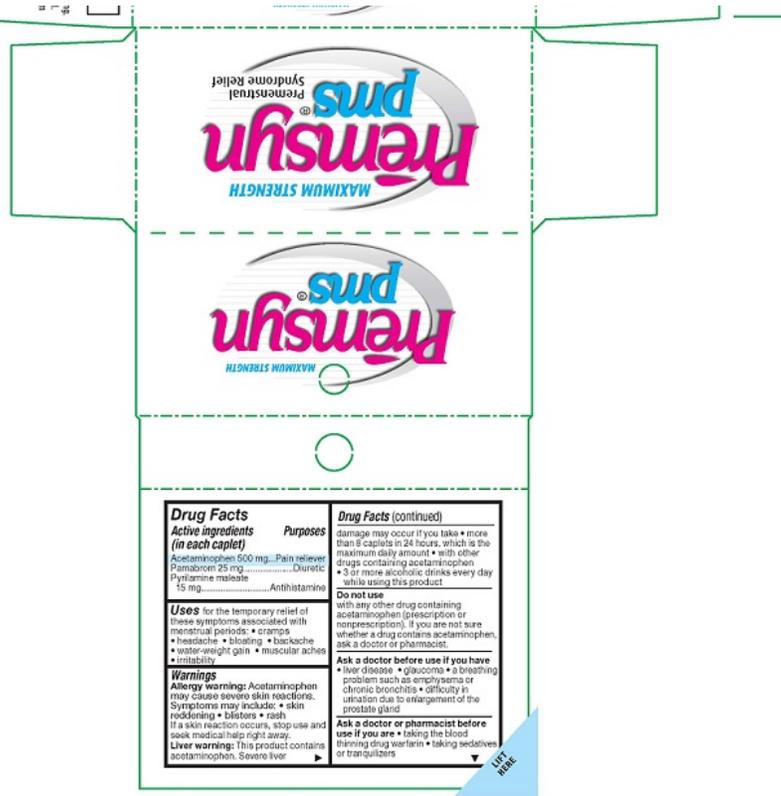
Varnish: aqueous (gloss) UV (gloss)

Print: color black 4-color

CP logo

CPG Item #: 5141/40CC
Product ID: 11999
Dedline #: 28267

IFC PROOF Date:



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 not final | part343 | 10/13/2017 | |

Labeler - Focus Consumer Healthcare, LLC (080743737)

Revised: 6/2020

Focus Consumer Healthcare, LLC