

## **LEADER PREMENSTRUAL - acetaminophen, pamabrom, pyrilamine maleate capsule** **Cardinal 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.*

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### **Leader Maximum Strength Premenstrual Relief**

#### **Active Ingredients (in each caplet)**

Acetaminophen 500mg  
Pamabrom 25mg  
Pyrilamine Maleate 15mg

#### **Purpose**

Pain Reliever  
Diuretic  
Antihistimine/Diuretic

#### **Uses**

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

- cramps
- bloating
- breast tenderness

#### **Warnings**

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 4 doses in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks everyday while using this product

**Overdose warning: Taking more than the recommended dose (overdose) could cause serious health problems.** In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms. **Do not exceed recommended dose.**

#### **Do not use**

- with other products containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, as a doctor or pharmacist.

#### **As a doctor before use if you have**

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

#### **Ask a doctor or pharmacist before use if you are**

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

**When using this product**

- you may get drowsy
- excitability may occur especially in children
- alcohol, sedatives and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery.

**Stop use and ask a doctor if**

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

**Pregnant or breast-feeding**

ask a health professional before use

**Keep out of reach of children.****Directions**

- do not take more than the recommended dose (see **Overdose warning**)
- **adults and children 12 years of age and older:** take 2 caplets with water
- repeat every 6 hours, as needed
- do not exceed 8 caplets per day
- **children under 12 years of age:** consult a doctor

**Other information**

store at 15-30degreesC (59-86degreesF)

**Inactive Ingredients**

croscarmellose sodium, hypromellose, magnesium silicate, magnesium stearate, microcrystalline cellulose, mineral oil, polyvinylpyrrolidone, pregelatinized starch, silica, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide, and triacetin.

**Questions or comments?**

Call toll free 1-800-200-6313

**Package labeling**

SEE NEW WARNINGS INFORMATION    NDC 37205-339-62

Leader Maximum Strength Premenstrual Relief

Acetaminophen

Pamabrom, Pyrilamine Maleate

Relieves: Cramps, Bloating, Tenderness

24 caplets

Distributed By Cardinal Health  
Dublin, Ohio 43017  
CIN 3468287  
www.myleader.com 1-800-200-6313

All Leader brand products are 100% satisfaction guaranteed or return to place of purchase for full refund.

**KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

**Drug Facts (continued)**  
**Inactive ingredients** croscarmellose sodium, hypromellose, magnesium silicate, magnesium stearate, microcrystalline cellulose, mineral oil, polyvinylpyrrolidone, pregelatinized starch, silica, sodium lauryl sulfate, sodium starch glycolate, stearic acid, titanium dioxide, and triacetin.

**Questions or comments?** Call toll free 1-800-200-6313

**SEE NEW WARNINGS INFORMATION**

**LEADER®**

NDC 37205-339-62

**MAXIMUM STRENGTH**

# Premenstrual Relief

**Acetaminophen,  
Pamabrom, Pyrilamine Maleate**

Relieves:  
• Cramps • Bloating • Tenderness



**24 CAPLETS**

**DISTRIBUTED BY CARDINAL HEALTH**  
DUBLIN, OHIO 43017  
CIN 3468287  
www.myleader.com 1-800-200-6313

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to place of purchase for a full refund.

PLD-A  
FC000227



0 96295 11189 7

## Drug Facts

### Active ingredients (in each caplet)

| Active ingredients (in each caplet) | Purpose                |
|-------------------------------------|------------------------|
| Acetaminophen 500 mg.....           | Pain reliever          |
| Pamabrom 25 mg.....                 | Diuretic               |
| Pyrilamine Maleate 15 mg.....       | Antihistamine/Diuretic |

**Uses** for the temporary relief of these symptoms associated with menstrual periods:  
 ■ cramps ■ bloating ■ breast tenderness

### Warnings

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take: ■ more than 4 doses 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

**Overdose warning:** Taking more than the recommended dose (overdose) could cause serious health problems. In case of overdose, get medical help or contact a Poison Control Center right away. Prompt medical attention is critical for adults as well as children even if you do not notice any signs or symptoms. **Do not exceed recommended dose.**

**Do not use** ■ with other products 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 ■ difficulty in urination due to an enlargement of the prostate gland ■ a breathing problem such as emphysema or chronic bronchitis

**Ask a doctor or pharmacist before use if you are** ■ taking sedatives or tranquilizers ■ taking the blood thinning drug warfarin

**When using this product** ■ you may get drowsy ■ excitability may occur especially in children ■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ avoid alcoholic drinks ■ be careful when driving a motor vehicle or operating machinery

**Stop use and ask a doctor if** ■ new symptoms occur ■ redness or swelling is present ■ pain gets worse or lasts more than 10 days

**If pregnant or breast-feeding,** ask a health professional before use. **Keep out of reach of children.**

**Directions** ■ do not take more than the recommended dose (see **Overdose warning**) ■ **adults and children 12 years of age and older:** take 2 caplets with water ■ repeat every 6 hours, as needed ■ **do not exceed 8 caplets per day** ■ **children under 12 years of age:** consult a doctor

**Other information** ■ store at 15°-30°C (59°-86°F)

Exp. Date:

Lot No.:

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

## LEADER PREMENSTRUAL

acetaminophen, pamabrom, pyrilamine maleate capsule

### Product Information

|                         |                |                    |               |
|-------------------------|----------------|--------------------|---------------|
| Product Type            | HUMAN OTC DRUG | Item Code (Source) | NDC:37205-339 |
| 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) (PAMABROM - UNII:UA8U0KJM72)             | PAMABROM           | 25 mg    |
| PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL) | PYRILAMINE MALEATE | 15 mg    |

### Inactive Ingredients

| Ingredient Name | Strength |
|-----------------|----------|
|-----------------|----------|

|   |
|---|
| <b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)                 |
| <b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)                         |
| <b>POLYETHYLENE GLYCOLS</b> (UNII: 3WJQ0SDW1A)                  |
| <b>MAGNESIUM SILICATE</b> (UNII: 9B9691B2N9)                    |
| <b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)                    |
| <b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)           |
| <b>MINERAL OIL</b> (UNII: T5L8T28FGP)                           |
| <b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)                       |
| <b>SODIUM LAURYL SULFATE</b> (UNII: 368GB5141J)                 |
| <b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2) |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                          |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                      |
| <b>TRIACETIN</b> (UNII: XHX3C3X673)                             |

### Product Characteristics

|                 |               |                     |          |
|-----------------|---------------|---------------------|----------|
| <b>Color</b>    | white (WHITE) | <b>Score</b>        | no score |
| <b>Shape</b>    | OVAL (OVAL)   | <b>Size</b>         | 7mm      |
| <b>Flavor</b>   |               | <b>Imprint Code</b> | CPC2826  |
| <b>Contains</b> |               |                     |          |

### Packaging

| # | Item Code        | Package Description  | Marketing Start Date | Marketing End Date |
|---|------------------|----------------------|----------------------|--------------------|
| 1 | NDC:37205-339-62 | 24 in 1 BLISTER PACK |                      |                    |

### Marketing Information

| Marketing Category      | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|-------------------------|--|----------------------|--------------------|
| OTC monograph not final | part343                                  | 02/28/2012           |                    |

**Labeler** - Cardinal Health (097537435)