

**PAIN AID PMF - acetaminophen, pamabrom tablet**  
**Zee Medical Inc**

*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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**Drug Facts**

Active Ingredient (in each tablet) Acetaminophen 500mg, Pamabrom 25 mg

Purpose-Pain Reliever, Diuretic

Uses

temporarily relieves the following menstrual and premenstrual symptoms:

- water-weight gain ■ bloating
- backache ■ headache ■ minor pain of menstrual and premenstrual cramps

Directions ■ adults: take 2 caplets every 6 hours, not more than 8 caplets in 24 hours ■ children under 12 years: ask a doctor

Warnings

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

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

Stop use and ask a doctor if

- pain lasts more than 10 days or gets worse
- redness or swelling is present in the painful area
- any new symptoms appear

If pregnant or breast-feeding baby, 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Inactive ingredients

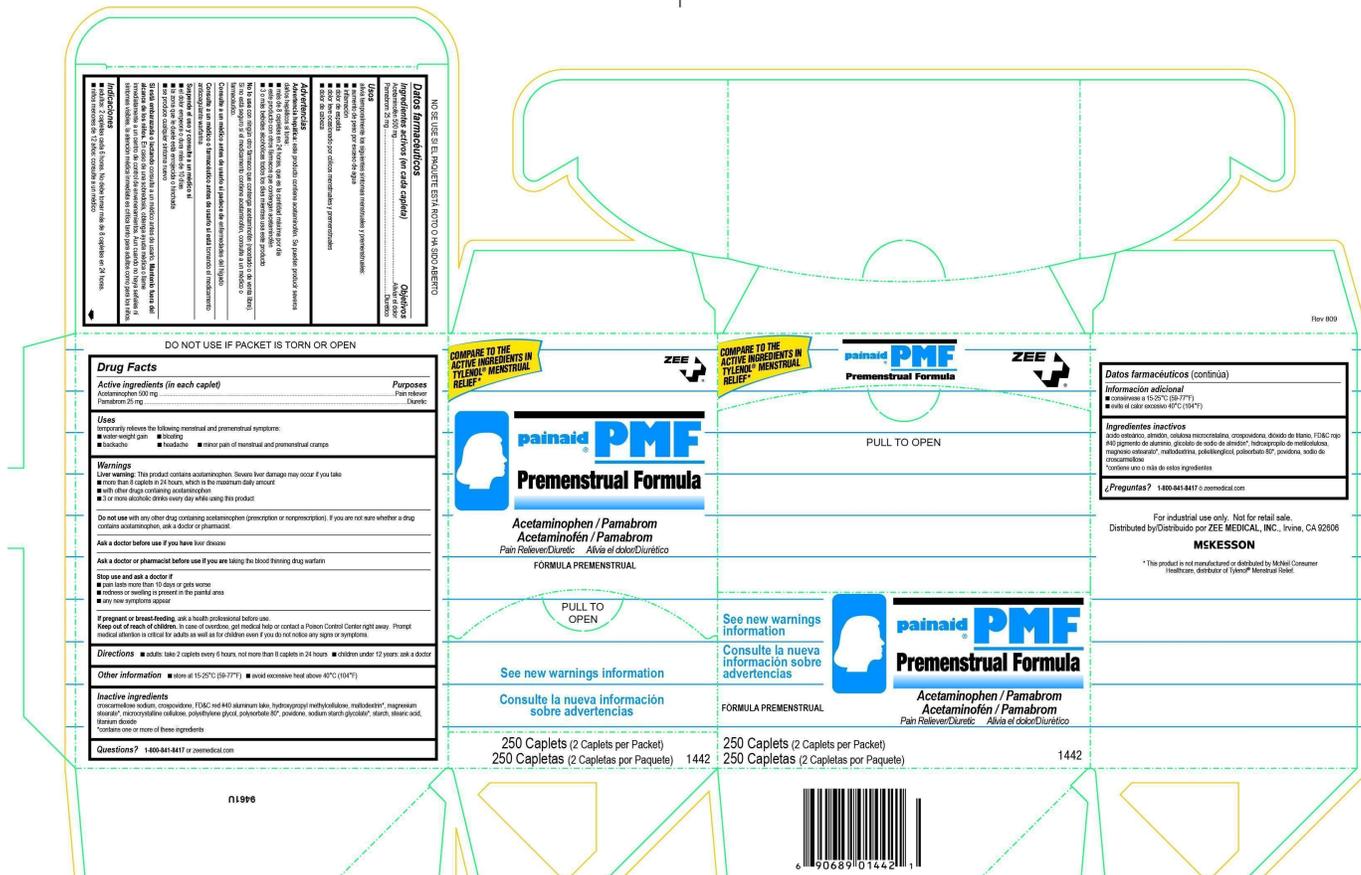
croscarmellose sodium, crospovidone, FDC red 40 aluminum lake, hydroxypropyl methylcellulose, maltodextrin\*, magnesium

stearate\*, microcrystalline cellulose, polyethylene glycol, polysorbate 80\*, povidone, sodium starch glycolate\*, starch, stearic acid,

titanium dioxide

\*contains one or more of these ingredients

MM1



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## PAIN AID PMF

acetaminophen, pamabrom tablet

### Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:35418-710 |
| <b>Route of Administration</b> | 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    |

### Inactive Ingredients

| Ingredient Name                                | Strength |
|--|----------|
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48)        |          |
| CROSPVIDONE (UNII: 68401960MK)                 |          |
| MAGNESIUM STEARATE (UNII: 70097M6I30)          |          |
| MALTODEXTRIN (UNII: 7CVR7L4A2D)                |          |
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) |          |
| POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)    |          |

|   |  |
|---|--|
| <b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)                        |  |
| <b>POVIDONE K29/32</b> (UNII: 390RMW2PEQ)                       |  |
| <b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)                      |  |
| <b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)                          |  |
| <b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2) |  |
| <b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)                   |  |

### Product Characteristics

|                 |                  |                     |          |
|-----------------|------------------|---------------------|----------|
| <b>Color</b>    | pink (rose pink) | <b>Score</b>        | no score |
| <b>Shape</b>    | CAPSULE (ZEE;PM) | <b>Size</b>         | 18mm     |
| <b>Flavor</b>   |                  | <b>Imprint Code</b> | ZEE;PM   |
| <b>Contains</b> |                  |                     |          |

### Packaging

| # | Item Code        | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|---------------------|----------------------|--------------------|
| 1 | NDC:35418-710-68 | 50 in 1 CARTON      |                      |                    |
| 1 | NDC:35418-710-67 | 125 in 1 CARTON     |                      |                    |
| 1 | NDC:35418-710-02 | 2 in 1 PACKET       |                      |                    |

### Marketing Information

| Marketing Category       | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------------|--|----------------------|--------------------|
| OTC mono graph not final | part343                                  | 06/12/2012           |                    |

**Labeler** - Zee Medical Inc (009645623)

**Registrant** - Ultra Seal Corporation (085752004)

### Establishment

| Name                        | Address | ID/FEI    | Business Operations    |
|-----------------------------|---------|-----------|------------------------|
| Ultratab Laboratories, Inc. |         | 151051757 | manufacture(35418-710) |

### Establishment

| Name                   | Address | ID/FEI    | Business Operations |
|------------------------|---------|-----------|---------------------|
| Ultra Seal Corporation |         | 085752004 | repack(35418-710)   |

Revised: 11/2012

Zee Medical Inc