

UNISHIELD CRAMP- acetaminophen, pamabrom tablet, film coated

Unishield

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.

Unishield Cramp Tabs

Drug Facts

Active ingredient (in each tablet)

Acetaminophen 325 mg

Pamabrom 25 mg

Purpose

Pain reliever/fever reducer

Diuretic

Uses

Temporarily relieves headache, bloating, cramps, backache, water-weight gain, muscular aches and pains associated with the menstrual period.

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, which is the maximum daily amount
- 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

If a skin reaction occurs, stop use and seek medical help right away.

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.
- for more than 10 days for pain unless directed by a doctor
- for more than 3 days for fever unless directed by a doctor

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

When using this product do not exceed recommended dose.

Stop use and ask a doctor if

- symptoms do not improve
- new symptoms occur
- pain or fever persists or gets worse
- 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. Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- drink 6 to 8 glasses of water each day while you are taking the tablets

Adults and children: (12 years and older) Take 2 tablets every 4 to 6 hours as needed.

Do not take more than 8 tablets in 24 hours.

Children under 12 years: Ask a doctor

Other information

- store at room temperature 59°-86°F (15°-30°C)
- avoid excessive heat and humidity
- tamper-evident sealed packets
- do not use any opened or torn packets

Inactive ingredients

D&C yellow #10, FD&C blue #1, FD&C red #40, microcrystalline cellulose, povidone, starch, stearic acid, sucrose

Questions or comments? 800-480-5856

Unishield Cramp Tabs

Unishield

Cramp Tabs

Menstrual Relief

100 Tablets/ 1 Tablet Per Packet

Acetaminophen 325 mg

Pamabrom 25 mg

Pull To Open

This Package is for Households without Young Children.

- Reduces water-weight gain
- Relieves headaches, backaches and muscular aches & pains

Relieves Cramps and Bloating

Tamper Evident Unit Dose Packets



UNISHIELD CRAMP

acetaminophen, pamabrom tablet, film coated

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|----------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:49314-8103 |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|---|-------------------|----------|
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | ACETAMINOPHEN | 325 mg |
| PAMABROM (UNII: UA8U0KJM72) (BROMOTHEOPHYLLINE - UNII:FZG87K1MQ6) | PAMABROM | 25 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|---|----------|
| CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U) | |
| D&C YELLOW NO. 10 (UNII: 35SW5USQ3G) | |
| SUCROSE (UNII: C151H8M554) | |
| FD&C BLUE NO. 1 (UNII: H3R47K3TBD) | |
| FD&C RED NO. 40 (UNII: WZB9127XOA) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| POVIDONE (UNII: FZ989GH94E) | |
| STEARIC ACID (UNII: 4ELV7Z65AP) | |

Product Characteristics

| | | | |
|-----------------|--------------------------------|---------------------|----------|
| Color | white (red and green crystals) | Score | no score |
| Shape | ROUND | Size | 11mm |
| Flavor | | Imprint Code | FR;7 |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|--|----------------------|--------------------|
| 1 | NDC:49314-8103-3 | 50 in 1 BOX | 03/01/2021 | |
| 1 | | 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 not final | part343 | 03/01/2021 | |

Labeler - Unishield (790677053)

Registrant - Unifirst First Aid Corporation (832947092)

Revised: 3/2022

Unishield