

MENSTRUAL RELIEF- acetaminophen, caffeine and pyrilamine maleate 500 mg, 60 mg and 15 mg tablet

We Care Distributor 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.

Menstrual Relief - Acetaminophen, Caffeine and Ppyrilamine Maleate

Drug Facts

Active Ingredient (in each tablet)	Purpose
Acetaminophen 500 mg	Pain reliever
Caffeine 60 mg	Diuretic
Ppyrilamine Maleate 15 mg	Antihistamine

Uses

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

- cramps
- bloating
- water-weight gain
- headache
- backache
- muscle aches
- fatigue

Warnings

Liver warning:

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

- more than 6 tablets in 24 hours, which is the maximum daily amount for this product
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

Allergy alert:

acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- skin reddening
- blisters
- rash
- hives
- facial swelling
- asthma (wheezing)
- shock

If a skin or general allergic 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.
- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

- liver disease
- glaucoma
- difficulty in urination due to 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 the blood thinning drug warfarin
- taking sedatives or tranquilizers

When using this product

- you may get drowsy
- avoid alcoholic drinks
- excitability may occur, especially in children
- alcohol, sedatives, and tranquilizers may increase drowsiness
- be careful when driving a motor vehicle or operating machinery
- limit the use of caffeine-containing medications, foods, or beverages because too much caffeine may cause nervousness, irritability, sleeplessness, and, occasionally, rapid heartbeat. The recommended dose of this product contains about as much caffeine as a cup of coffee.

Stop use and ask a doctor if

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

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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

Directions

- **do not take more than the recommended dose**
- **adults and children 12 years and over:** take 2 tablets with water. Repeat every 6 hours, as needed; do not exceed 6 tablets per day
- **children under 12 years:** consult a doctor

Other information

- store at room temperature
- read all product information before using. Keep this box for important information

Inactive ingredients

colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene

glycol, polyvinyl pyrrolodine, pregelatinized starch, titanium dioxide, talc

Questions or comments?

1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com

PRINCIPAL DISPLAY PANEL

See New Warnings Information & Directions

Compare to the Active Ingredients in
Midol Complete

Acetaminophen, Caffeine and Ppyrilamine Maleate Tablets, 500 mg, 60 mg and 15 mg

TO OPEN

PUSH IN TAB AND PULL OUT

25 Pouches of 2 Tablets Each

NDC: 70005-011-25



MENSTRUAL RELIEF

COMPARE TO ACTIVE INGREDIENTS IN
Midol Complete®*

Acetaminophen - Pain Reliever
Caffeine - Diuretic
Pyrilamine maleate - Antihistamine

Multi-Symptom Relief of:

- Cramps
- Bloating
- Fatigue
- Backache & Headache

*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark Midol® Complete.

25 Pouches of 2 Coated Tablets

Drug Facts

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Acetaminophen 500 mg	Pain reliever
Caffeine 60 mg	Diuretic
Pyrilamine maleate 15 mg	Antihistamine

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- cramps ■ bloating ■ water-weight gain
- headache ■ backache ■ muscle aches ■ fatigue

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Do not use

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- if you have ever had an allergic reaction to this product or any of its ingredients

Ask a doctor before use if you have

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

Ask a doctor or pharmacist before use if you are

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Drug Facts (continued)

Directions

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adults and children 12 years and older:	take 2 tablets with water. Repeat every 6 hours, as needed do not exceed 6 tablets per day
children under 12 years:	consult a doctor

Other information store at room temperature

Inactive ingredients colloidal silicon dioxide, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl pyrrolodine, pregelatinized starch, titanium dioxide, talc

Questions or comments? 1-888-705-WECARE (Mon-Fri 9am-5pm EST) or www.wecaredistributor.com



Manufactured For / Distributed By:
We Care Distributor Inc.
Hermitage, TN 37076
www.wecaredistributor.com

**DO NOT USE IF POUCH IS
BROKEN OR TORN**

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MENSTRUAL RELIEF

acetaminophen, caffeine and pyrilamine maleate 500 mg, 60 mg and 15 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70005-011
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	15 mg
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	60 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
N-VINYLPYRROLIDINE (UNII: BGQ0JZ9FNA)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	CH
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70005-011-25	25 in 1 BOX		
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:70005-011-50	50 in 1 BOX		
2		2 in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:70005-011-02	2 in 1 POUCH		
3		2 in 1 POUCH; 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	02/15/2016	

Labeler - We Care Distributor Inc. (079832998)

Establishment

Name	Address	ID/FEI	Business Operations
Elysium Pharmaceutical Ltd.		915664486	manufacture(70005-011)