

MENSTRUAL RELIEF- acetaminophen, caffeine and pyrilamine maleate tablet TOP CARE (Topco Associates 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.

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Caffeine 60 mg

Pyrilamine maleate 15 mg

Purpose

Pain reliever

Diuretic

Antihistamine

Uses

- for the temporary relief of these symptoms associated with menstrual periods
 - cramps
 - bloating
 - fatigue
 - backache
 - water-weight gain
 - headache
 - muscle aches

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
- 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.
- 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

- drowsiness may occur
- 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

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

These could be signs of a serious condition.

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 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 older

- take 2 caplets with water
- repeat every 6 hours, as needed
- do not take more than 6 caplets in 24 hours
- children under 12 years: consult a doctor

Other information

- store at 25°C (77°F); excursions permitted between 15-30°C (59-86° F)

Inactive ingredients

colloidal silicon dioxide, croscarmellose sodium, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, mineral oil, povidone, pregelatinized starch, stearic acid, titanium dioxide

Questions or comments?

Call toll free **1-888-423-0139**

Principal Display Panel

COMPARE TO MIDOL® COMPLETE ACTIVE INGREDIENTS*

MAXIMUM STRENGTH SUPPORTING THE FIGHT AGAINST BREAST CANCER†

Menstrual Relief

ACETAMINOPHEN, CAFFEINE, PYRILAMINE MALEATE

PAIN RELIEVER • DIURETIC • ANTIHISTAMINE

MULTI-SYMPTOM RELIEF OF:

- Cramps
- Bloating
- Fatigue
- Backache
- Headache

CAPLETS

*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Midol® Complete.

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BLISTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

DISTRIBUTED BY: TOPCO ASSOCIATES LLC

ELK GROVE VILLAGE, IL 60007 ©TOPCO

QUESTIONS? 1-888-423-0139

topcare@topcare.com

Product Label

<p>Drug Facts (continued)</p> <p>Warnings</p> <p>Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:</p> <ul style="list-style-type: none"> more than 4,000 mg of acetaminophen in 24 hours with other drugs containing acetaminophen 3 or more alcoholic drinks every day while using this product. <p>Allergy alert: Acetaminophen may cause severe skin reactions. Symptoms may include:</p> <ul style="list-style-type: none"> skin reddening blisters rash <p>If a skin reaction occurs, stop use and seek medical help right away.</p> <p>Do not use</p> <ul style="list-style-type: none"> 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 <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> liver disease glaucoma difficulty in urination due to enlargement of the prostate gland <p>Ask a doctor or pharmacist before use if you are</p> <ul style="list-style-type: none"> taking the blood thinning drug warfarin taking sedatives or tranquilizers <p>When using this product</p> <ul style="list-style-type: none"> avoid alcoholic drinks excitability may occur, especially in children 	<p>Drug Facts (continued)</p> <p>Directions</p> <ul style="list-style-type: none"> do not take more than the recommended dose adults and children 12 years and older take 2 caplets with water repeat every 6 hours, as needed do not take more than 6 caplets in 24 hours children under 12 years: consult a doctor
<p>Drug Facts (continued)</p> <p>Warnings</p> <ul style="list-style-type: none"> 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. <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> new symptoms occur redness or swelling is present pain gets worse or lasts more than 10 days fever gets worse or lasts more than 3 days <p>These could be signs of a serious condition.</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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 children even if you do not notice any signs or symptoms.</p>	<p>Drug Facts (continued)</p> <p>Uses</p> <ul style="list-style-type: none"> for the temporary relief of these symptoms associated with menstrual periods cramps bloating backache water-weight gain muscle aches fatigue headache

<p>Drug Facts</p> <p>Active ingredients (in each caplet)</p> <ul style="list-style-type: none"> Acetaminophen 500 mg.....Pain reliever Caffeine 60 mg.....Diuretic Pyrilamine maleate 15 mg.....Antihistamine 	<p>Drug Facts (continued)</p>
--	--------------------------------------



COMPARE TO MIDOL® COMPLETE ACTIVE INGREDIENTS*

SUPPORTING THE FIGHT AGAINST BREAST CANCER



Menstrual Relief

ACETAMINOPHEN, CAFFEINE, PYRILAMINE MALEATE
PAIN RELIEVER • DIURETIC • ANTIHISTAMINE

MULTI-SYMPTOM RELIEF OF:

- Cramps
- Headache
- Bloating
- Backache
- Fatigue




actual size

24 CAPLETS

Other information

- store at 25°C (77°F); excursions permitted between 15-30°C (59-86°F)

Inactive ingredients

colloidal silicon dioxide,

Questions or comments?

Call toll free 1-888-423-0139

TAMPER EVIDENT: DO NOT USE IF CARTON IS OPENED OR IF BULSTER UNIT IS TORN, BROKEN OR SHOWS ANY SIGNS OF TAMPERING.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Lot No.:

Exp. Date:

DISTRIBUTED BY: TOPCO ASSOCIATES, LLC
 ELK GROVE VILLAGE, IL 60007 ©TOPCO PIVA0318
 QUESTIONS? 1-888-423-0139
 topcare@topco.com www.topcarebrand.com
 *TopCare® proudly donates a portion of this purchase to breast cancer early detection and research.

QUALITY GUARANTEED
 P.L.D.-E168E FCC004510

*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Midol® Complete.

0 36800 13830 8

TOPCARE HEALTH Menstrual Relief**MENSTRUAL RELIEF**

acetaminophen, caffeine and pyrilamine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-187
Route of Administration	ORAL		

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONE (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	white	Score	no score
Shape	CAPSULE	Size	17mm
Flavor		Imprint Code	TCL347
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-187-24	24 in 1 CARTON	03/31/2014	
1		1 in 1 BLISTER PACK; 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	03/31/2014	

Labeler - TOP CARE (Topco Associates LLC) (006935977)

Revised: 12/2022

TOP CARE (Topco Associates LLC)