

MENSTRUAL RELIEF- acetaminophen, caffeine and pyrilamine maleate tablet
Freds 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.

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 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 are allergic to acetaminophen or any of the inactive ingredients in this product

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
- 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 lasts 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 right away.

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°C- 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 1-877-753-3935 Monday- Friday 9AM-5PM EST

Principal Display Panel

Maximum Strength

Menstrual Relief Caplets

Acetaminophen, Caffeine, Pyrilamine maleate

Pain Reliever / Diuretic / Antihistamine

Multi-Symptom Relief of:

Cramps

Bloating

Fatigue

Backache & Headache

Caplets

Compare to the active ingredients in Midol® Complete †

† 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: fred's, Inc.

4300 NEW GETWELL RD, MEMPHIS, TN 38118

www.fredsinc.com

Product Label

COATING
FREE AREA



Drug Facts (continued)

Warnings: 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

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

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.

If pregnant or breast-feeding, ask a health professional before use.

Stop use and ask a doctor if
 ■ fever gets worse or lasts more than 3 days
 ■ pain gets worse or lasts more than 10 days
 ■ redness or swelling is present
 ■ new symptoms occur

Drug Facts (continued)

■ 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.

Drug Facts (continued)

Active ingredients (in each caplet)
 Acetaminophen 500 mg Pain reliever
 Caffeine 60 mg Diuretic
 Pyrilamine maleate 15 mg Antihistamine

Purposes
 ■ for the temporary relief of these symptoms associated with menstrual periods ■ cramps ■ bloating

Uses
 ■ fatigue ■ backache ■ water-weight gain
 ■ headache ■ muscle aches

Drug Facts (continued)

NDC 55315-183-24

Actual Size



fred's®

**Maximum Strength
Menstrual Relief Caplets**
 Acetaminophen, Caffeine, Pyrilamine Maleate
 Pain Reliever/Diuretic/Antihistamine
 Multi-Symptom Relief of:
 Cramps
 Bloating
 Fatigue
 Backache & Headache
 24 Caplets



Lab Tested for Quality,
Fred Tested for Satisfaction

*Compare to the active ingredients in:
Midol® Complete



SUPPORTING THE FIGHT
AGAINST BREAST CANCER®

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.

Lot No.:
Exp. Date:

*Fred's® proudly donates a portion of each purchase to breast cancer early detection and research.
DISTRIBUTED BY: fred's, Inc.
4300 NEW GETWELL RD, MEMPHIS, TN 38118
www.fredinc.com

This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of Midol® Complete.
P.D.-C168D
F0002752
0 84579 10613 4

fred's Promise
Not Happy With The Product?
Just Bring It Back for a Refund!



Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Questions or comments?

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

Drug Facts (continued)**Inactive ingredients** colloidal silicon dioxide,

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

Other information**Drug Facts** (continued)31
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00/00**Fred's Menstrual Relief Caplets****MENSTRUAL RELIEF**

acetaminophen, caffeine and pyrilamine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55315-183
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (15 MPAS AT 5%) (UNII: 68401960MK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
MINERAL OIL (UNII: T5L8T28FGP)	
POVIDONES (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:55315-183-24	2 in 1 CARTON		

1	12 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	10/15/2012	

Labeler - Freds Inc (005866116)

Revised: 8/2015

Freds Inc