# 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.

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## **Drug Facts**

# Active ingredients (in each caplet)

## Acetaminophen 500 mg

Caffeine 60 mg Pyrilamine maleate 15 mg

# Purpose

#### Pain reliever

Stimulant Diuretic

#### Uses

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

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

## **Warnings**

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 6 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
- 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 while taking this product 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 appear
- redness or swelling is present
- pain gets worse or lasts more than 10 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. Quick medical attention is critical for adults as well 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 older: take 2 caplets with water (1,000 mg) every 6 hours while symptoms last
- Do not take more than 6 caplets (3,000 mg) in 24 hours, unless directed by a doctor
- 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, and titanium dioxide

#### Questions or comments?

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

### **Principal Display Panel**

Compare to the active ingredients in Midol® Complete †

† This product is not manufactured or distributed by Bayer Healthcare LLC, owner of the registered trademark Midol® Complete

Maximum strength

# **Menstrual Relief Caplets**

Acetaminophen 500 mg, Caffeine 60 mg, Pyrilamine maleate 15 mg

Pain Reliever / Stimulant / Diuretic

MULTI SYMPTOM RELIEF OF:

cramps, bloating, fatigue, backache & headache

THIS PRODUCT IS PACKAGED IN A CHILD RESISTANT AND TAMPER EVIDENT PACKAGE. USE ONLY IF BLISTERS ARE INTACT.

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

**Product Label** 



### **MENSTRUAL RELIEF**

acetaminophen, caffeine and pyrilamine maleate tablet

Product Information				
Product Type	HUMAN OTC DRUG LABEL	Item Code (Source)	NDC:55315-183	
Route of Administration	ORAL	DEA Schedule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
ACETAMINO PHEN (ACETAMINO PHEN)	ACETAMINOPHEN	500 mg	
CAFFEINE (CAFFEINE)	CAFFEINE	60 mg	
PYRILAMINE MALEATE (PYRILAMINE)	PYRILAMINE MALEATE	15 mg	

Inactive Ingredients			
Ingredient Name	Strength		
SILICON DIO XIDE			
CROSCARMELLOSE SODIUM			
CROSPOVIDONE			
HYPROMELLOSES			
MAGNESIUM STEARATE			
CELLULOSE, MICRO CRYSTALLINE			
MINERAL OIL			
POVIDONES			
STARCH, CORN			
STEARIC ACID			
TITANIUM DIO XIDE			

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		

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)

# **Registrant** - P and L Development of New York Corporation (800014821)

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