

MENSTRUAL RELIEF - acetaminophen,caffeine,pyrilamine tablet

Velocity Pharma

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.

Acetaminophen, Caffeine, Diuretic, Pyrilamine Maleate, Antihistamine

Active Ingredient

(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
- Water-weight gain
- Headache
- Backache
- Muscle aches
- Fatigue

Warnings

SEE BOTTLE FOR ADDITIONAL WARNINGS AND PRODUCT INFORMATION.

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 for this product
- With other drug 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.
- 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 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. 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 older:**
- take 2 caplets with water
- repeat every 6 hours, as needed
- do not exceed 6 caplets per day
- **Children under 12 years: ask a doctor.**

Other Information

- Store at a controlled temperature between 62 and 77 degrees F

Inactive Ingredients

Carnauba wax, croscarmellose sodium, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, micro-crystalline cellulose, pregelatinized starch, propylene glycol, shellac, titanium dioxide, triacetin

Questions?

Call 1-855-314-1850

TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING

Distributed by: Velocity Pharma LLC

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 076168-064-03

Velocity

Menstrual Relief

Complete Formula

20 CAPLETS
Acetaminophen, Caffeine,
Pyrilamine Maleate,
Antihistamine

Do not use if imprinted safety seal under cap is broken or missing.

Drug Facts

Active ingredient (in each caplet)

Purpose

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

Uses:

for the temporary relief of these symptom associated with menstrual periods.

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

Warnings:

Keep outer carton for complete warnings and product information.

- Liver Warning ■ Do not Use ■ Ask a Doctor Before Using ■ Ask a Pharmacist Before Using
- When Using This Product ■ Stop Use and Ask a Doctor if ■ If Pregnant ■ Keep Out of Reach of Children.

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Children under 12 years: ask a doctor.

Distributed by **VELOCITY PHARMA LLC**
226 B Sherwood Avenue
Farmingdale, NY 11735

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Drug Facts (continued)

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.

Drug Facts (continued)

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.

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Inactive Ingredients: carnauba wax, croscarmellose sodium, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, micro-crystalline cellulose, pregelatinized starch, propylene glycol, shellac, titanium dioxide, triacetin.

Directions Do not take more than the recommended dose

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- **Children under 12 years: ask a doctor.**

Questions or Comments?
1-855-314-1850

20
CAPLETS

Acetaminophen, Caffeine, Diuretic,
Pyrilamine Maleate, Antihistamine

Velocity
Menstrual
Relief
Complete Formula

Compare to the active
ingredient in Mildol[®]
Complete *

NDC 076168-064-03

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Active ingredients (in each caplet)

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NDC: 76168-064-03 –20 COUNT

Enteric Coated to help prevent upset stomach

MENSTRUAL RELIEF

acetaminophen,caffeine,pyrilamine tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:76168-064
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
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

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:76168-064-03	20 in 1 BOTTLE		
1		1 in 1 CARTON		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	05/01/2013	

Labeler - Velocity Pharma (962198409)

Registrant - Velocity Pharma (962198409)

Revised: 10/2013

Velocity Pharma