# MENSTRUAL COMPLETE- acetaminophen, caffeine, pyrilamine maleate tablet, film coated Kroger Company

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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### Kroger 44-390

## 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:

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

## 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

• difficulty in urination due to enlargement of the prostate gland

- liver disease
- glaucoma
- 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

- avoid alcoholic beverages
- excitability may occur, especially in children
- be careful when driving a motor vehicle or operating machinery
- alcohol, sedatives, and tranquilizers may increase drowsiness
- you may get drowsy
- 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 occur
- redness or swelling is present
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts 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 accidental overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away. Prompt 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 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

- see end flap for expiration date and lot number
- store at 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)

#### **Inactive ingredients**

corn starch, croscarmellose sodium, crospovidone, hypromellose, magnesium stearate, microcrystalline

cellulose, polydextrose, polyethylene glycol, povidone, silicon dioxide, stearic acid, titanium dioxide, triacetin

#### Questions or comments?

1-800-632-6900

### **Principal Display Panel**

**COMPARE TO** the active ingredients in **MIDOL**® **COMPLETE** •see side panel

NDC 30142-390-10

**Kroger®** 

**Maximum Strength** 

Menstrual Complete

**Acetaminophen,** Pain Reliever

Caffeine, Diuretic

Pyrilamine Maleate, Antihistamine

Relief of Cramps, Bloating, Fatigue,

Backache & Headache

actual size

**40** CAPLETS

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

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Kroger 44-390

#### MENSTRUAL COMPLETE

acetaminophen, caffeine, pyrilamine maleate tablet, film coated

#### **Product Information**

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-390
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ACETAMINO PHEN (UNII: 36209 ITL9D) (ACETAMINO PHEN - UNII: 36209 ITL9D)	ACETAMINOPHEN	500 mg
CAFFEINE (UNII: 3G6 A5W338E) (CAFFEINE - UNII:3G6 A5W338E)	CAFFEINE	60 mg
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	15 mg

Inactive Ingredients	
Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)	
CROSPO VIDO NE (UNII: 2S7830E561)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICRO CRYSTALLINE CELLULO SE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PO VIDO NE (UNII: FZ989 GH94E)	
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIO XIDE (UNII: 15FIX9 V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics				
Color	WHITE	Score	score with uneven pieces	
Shape	OVAL	Size	17mm	
Flavor		Imprint Code	44;390	
Contains				

P	ackaging			
#	Item Code	Package Description	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
1	NDC:30142-390-22	1 in 1 CARTON	06/03/2019	
1		48 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:30142-390-10	1 in 1 CARTON	06/03/2019	
2		40 in 1 BOTTLE; 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	06/03/2019		

## Labeler - Kroger Company (006999528)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(30142-390)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(30142-390)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(30142-390)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(30142-390)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(30142-390)

Revised: 5/2020 Kroger Company