

MENSTRUAL COMPLETE- acetaminophen, caffeine, pyrilamine maleate tablet, film coated
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.

TopCare 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
- water-weight gain
- cramps
- backache
- fatigue
- 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

- if you have ever had an allergic reaction to this product or any of its ingredients
- 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

- 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?

1-888-423-0139

Principal display panel

TopCare®
health™

COMPARE TO
MIDOL® COMPLETE
ACTIVE INGREDIENTS*

NDC 36800-391-08

MAXIMUM STRENGTH

Menstrual Complete

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

MULTI-SYMPTOM RELIEF OF:

- Cramps • Headache • Bloating
- Backache • Fatigue

24 CAPLETS

actual
size

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

*This product is not manufactured or distributed by Bayer
HealthCare LLC, owner of the registered trademark Midol®
Complete.

50844 ORG051739008

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TOPCO ASSOCIATES LLC
ELK GROVE VILLAGE, IL
60007

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QUESTIONS?

1-888-423-0139

topcare@topco.com

www.topcarebrand.com



COMPARE TO MIDOL® COMPLETE ACTIVE INGREDIENTS*

NDC 36800-391-08

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Drug Facts (continued)
Questions or comments? 1-888-423-0139



0 36800 45824 6

No print/No varnish
Lot & Exp date

B-1910-390-08-R
ORG051739008

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

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topcare@topco.com
www.topcarebrand.com

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Drug Facts (continued)

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■ taking other drugs

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Topcare 44-390

MENSTRUAL COMPLETE

acetaminophen, caffeine, pyrilamine maleate tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:36800-391
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
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
CROSPVIDONE (UNII: 2S7830E561)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	44;390
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:36800-391-08	1 in 1 CARTON	01/01/2019	
1		24 in 1 BOTTLE, PLASTIC; 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	01/01/2019	

Labeler - Topco Associates, LLC (006935977)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(36800-391)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(36800-391)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867837	PACK(36800-391)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		967626305	PACK(36800-391)

Establishment

Name	Address	ID/FEI	Business Operations
LNK International, Inc.		868734088	PACK(36800-391)