

MENSTRUAL RELIEF- acetaminophen, caffeine and pyrilamine maleate tablet

Target Corporation

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.

Target 44-390-Delisted

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

Warnings

Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (3,000 mg acetaminophen) in 24 hours. 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
- alcohol, sedatives and tranquilizers may increase
- avoid alcoholic drinks
- excitability may occur, especially in children
- 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

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.

Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help or contact a Poison Control Center right away.

Directions

- **do not take more than the recommended dose (see overdose warning)**
- adults and children 12 years and older:
 - take 2 caplets with water
 - repeat every 6 hours, as needed
 - do not exceed 8 caplets in 24 hours
- children under 12 years: ask a doctor

Other information

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

Inactive ingredients

cellulose, croscarmellose sodium, crospovidone, hypromellose, magnesium stearate, polydextrose, polyethylene glycol, povidone, silica gel, stearic acid, titanium dioxide, triacetin

Questions?

Call 1-800-910-6874

Principal Display Panel

NDC 11673-390-10

Compare to active ingredients in Midol® Menstrual Complete*

menstrual relief

maximum strength caplets

acetaminophen, 500 mg

caffeine, 60 mg

pyrilamine maleate, 15 mg

for relief of cramps, bloating, fatigue, headache and backache

up & up®

40 CAPLETS

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

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

OMIT B



NDC 11673-390-10

Compare to active ingredients in Midol® Menstrual Complete*



menstrual relief maximum strength caplets

acetaminophen, 500 mg
caffeine, 60 mg
pyrilamine maleate, 15 mg

pain reliever, diuretic,
antihistamine

for relief of cramps, bloating,
fatigue, headache and backache

40
CAPLETS

40 CAPLETS SHOWN ACTUAL SIZE ABOVE

**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.
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Drug Facts (continued)

KEEP OUTER PACKAGE FOR COMPLETE PRODUCT INFORMATION

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

Uses
■ for the temporary relief of these symptoms associated with menstrual periods:
■ cramps
■ muscle aches
■ fatigue
■ bloating
■ backache
■ water-weight gain
■ breast tenderness

Warnings
Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 6 caplets (3,000 mg acetaminophen) in 24 hours. 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

Drug Facts (continued)

Directions
■ do not take more than the recommended dose (see overdose warning)
■ 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 25°C (77°F); excursions permitted between 15°-30°C (59°-86°F)
■ see end flap for expiration date and lot number

Inactive ingredients corn starch, croscarmellose sodium, crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, silica gel, stearic acid, titanium dioxide, tricalcin

Questions? Call 1-800-910-6874

Drug Facts (continued)

When using this product
■ taking sedatives or tranquilizers
■ excitability may occur, especially in children
■ alcohol, sedatives, and tranquilizers may increase drowsiness ■ you may get drowsy
■ be careful when driving a motor vehicle or operating machinery ■ avoid alcoholic drinks

Ask a doctor or pharmacist before use if you are
■ a breathing problem such as emphysema or chronic bronchitis ■ glaucoma
■ difficulty in urination due to enlargement of the prostate gland ■ liver disease

Ask a doctor before use if you have
■ if you have ever had an allergic reaction to this product or any of its ingredients
■ not sure whether a drug contains acetaminophen, ask a doctor or pharmacist

Drug Facts (continued)

■ 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.

Keep out of reach of children.
Overdose warning: Taking more than the recommended dose (overdose) may cause liver damage. In case of overdose, get medical help

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REV0913C39010
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Target 44-390

MENSTRUAL RELIEF

acetaminophen, caffeine and pyrilamine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11673-390
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
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11673-390-10	1 in 1 CARTON		
1		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	04/29/2002	11/04/2018

Labeler - Target Corporation (006961700)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		038154464	PACK(11673-390)

Establishment			
Name	Address	ID/FEI	Business Operations
LNK International, Inc.		832867894	MANUFACTURE(11673-390)

Revised: 11/2015

Target Corporation