

MIDOL COMPLETE- acetaminophen, caffeine, and pyrilamine maleate tablet
Bayer HealthCare 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.

Midol® Complete

Drug Facts

<i>Active ingredients (in each caplet)</i>	<i>Purpose</i>
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
- bloating
- water-weight gain
- 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 for this product
- 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.
- 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 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

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: consult a doctor

Other information

store at room temperature

Inactive ingredients

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

Questions or comments?

1-800-331-4536 (Mon-Fri 9AM - 5PM EST) or www.midol.com

PRINCIPAL DISPLAY PANEL - 40 Caplet Bottle Carton

VALUE SIZE

**Midol[®]
Complete**

Acetaminophen/Caffeine/Pyrilamine Maleate
Pain Reliever/Diuretic/Antihistamine

MAXIMUM STRENGTH

**MULTI-SYMPTOM
RELIEF OF
CRAMPS, BLOATING
FATIGUE, BACKACHE
& HEADACHE
40 CAPLETS**

MIDOL COMPLETE

acetaminophen, caffeine, and pyrilamine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0280-8005
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)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	white	Score	no score
Shape	OVAL (oblong)	Size	17mm
Flavor		Imprint Code	MIDOL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-8005-16	2 in 1 CARTON	02/10/2014	
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
2	NDC:0280-8005-24	3 in 1 CARTON	02/10/2014	
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product		
3	NDC:0280-8005-40	1 in 1 CARTON	02/10/2014	
3		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	02/10/2014	

Labeler - Bayer HealthCare LLC. (112117283)

Revised: 11/2017

Bayer HealthCare LLC.