

MIDOL COMPLETE- acetaminophen, caffeine, and pyrilamine maleate tablet
R J General 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.

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 - 100 Caplet Pouch Carton

**Midol®
Complete**

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

**MAXIMUM STRENGTH
MULTI-SYMPTOM**

RELIEF OF

**CRAMPS, BLOATING
FATIGUE, BACKACHE
& HEADACHE**

50 POUCHES of 2 CAPLETS

Midol[®] Complete

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



MAXIMUM STRENGTH
MULTI-SYMP TOM
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Whippany, NJ 07981 USA

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Pain Reliever/Diuretic/Antihistamine



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0 26431 29732 1

This product is repackaged by RJ General Corp, 2350 Burnet Ave., Cincinnati, Ohio 45219
(513)621-3738 (Mon-Fri 9AM-3PM EST) from a product manufactured by Bayer.
Bayer[®], the Bayer Cross[®] and Midol[®] are registered trademarks of Bayer, used with permission.

Other information store at room temperature
Inactive ingredients carnauba wax, croscarmellose sodium, FD&C Blue #2 aluminum lake, glycol, shellac, titanium dioxide, triacetin
Questions or comments? 1-800-331-4536 or www.midol.com

Drug Facts

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

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

Warnings: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers/fever reducers. Acetaminophen may cause liver damage.
Do not use with any other product containing acetaminophen.
Ask a doctor before use if you have
 • 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 sedatives or tranquilizers
 • you may get drowsy
 • avoid alcoholic drinks
When using this product
 • 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

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 can cause serious health problems. 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 (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 per day
 • children under 12 years: consult a doctor

MIDOL COMPLETE

acetaminophen, caffeine, and pyrilamine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70264-012(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
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TRIACETIN (UNII: XHX3C3X673)	

CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
SHELLAC (UNII: 46N107B71O)	

Product Characteristics

Color	WHITE	Score	no score
Shape	OVAL	Size	17mm
Flavor		Imprint Code	MIDOL
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70264-012-01	50 in 1 CARTON	02/10/2014	
1		2 in 1 POUCH; 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 - R J General Corporation (122542830)

Establishment

Name	Address	ID/FEI	Business Operations
R J General Corporation		122542830	REPACK(70264-012)

Revised: 8/2018

R J General Corporation