

MIDOL COMPLETE- acetaminophen, caffeine, and pyrilamine maleate tablet

Your Safety 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.

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 - 25 Pouch Box

**Midol®
Complete**

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

**MAXIMUM STRENGTH
MULTI-SYMPTOM**

**RELIEF OF
CRAMPS, BLOATING
FATIGUE, BACKACHE
& HEADACHE
CAPLETS**

Midol[®] Complete

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



MAXIMUM STRENGTH | CRAMPS, BLOATING
MULTI-SYMPTOM | FATIGUE, BACKACHE
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CAPLETS

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



MAXIMUM STRENGTH | CRAMPS, BLOATING
MULTI-SYMPTOM | FATIGUE, BACKACHE
RELIEF OF | & HEADACHE



CAPLETS

25 Pouches
of
2 Caplets Each

#1442

Drug Facts	
Active ingredients (in each caplet)	
Acetaminophen 500 mg.....	Pain reliever
Caffeine 60 mg.....	Stimulant
Pyrilamine maleate 15 mg.....	Diuretic
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: 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 product 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 baby, 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	
Other information: store at room temperature	
Inactive ingredients: carnauba wax, crocarmellose sodium, FD&C blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose, pregelatinized starch, propylene glycol, shellac, titanium dioxide, triacetin	
Questions or comments? call 1-800-331-4536	

Midol Complete
 Acetaminophen/Caffeine/Pyrimidine Maleate
 Pain Reliever/Diuretic/Antihistamine

BAYER MAXIMUM STRENGTH | CRAMPS, BLOATING
 MULTI-SYMPTOM | FATIGUE, BACKACHE
 RELIEF OF | & HEADACHE

MIDOL COMPLETE
CAPLETS

Lot
 Exp

This Product is repackaged by Your Safety Company Inc,
 111 Quarry Road Chambersburg PA, 17202 (800)-548-3920
 (Mon - Fri 8:am -5:00 pm EST) from a product manufactured
 by Bayer. Bayer, the Bayer Cross and Midol are registered
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 LLC Whippany, NJ 07981

MIDOL COMPLETE
 acetaminophen, caffeine, and pyrilamine maleate tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70262-303(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:70262-303-25	25 in 1 BOX		
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	03/15/2016	

Establishment

Name	Address	ID/FEI	Business Operations
Your Safety Company		050622331	RELABEL(70262-303)

Revised: 3/2016

Your Safety Company