

MIDOL COMPLETE- acetaminophen, caffeine, and pyrilamine maleate tablet

R J General Corporation

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.

Allergy Alert

acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include:

- skin reddening
- blisters
- rash
- hives
- facial swelling
- asthma (wheezing)
- shock If a skin or general allergic reaction occurs, stop use and seek medical help

right away.

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.

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.

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.

Other information

- Store at room temperature. Avoid temperatures above 25°C (77°F).

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)

PRINCIPAL DISPLAY PANEL - 100 Caplet Pouch Carton

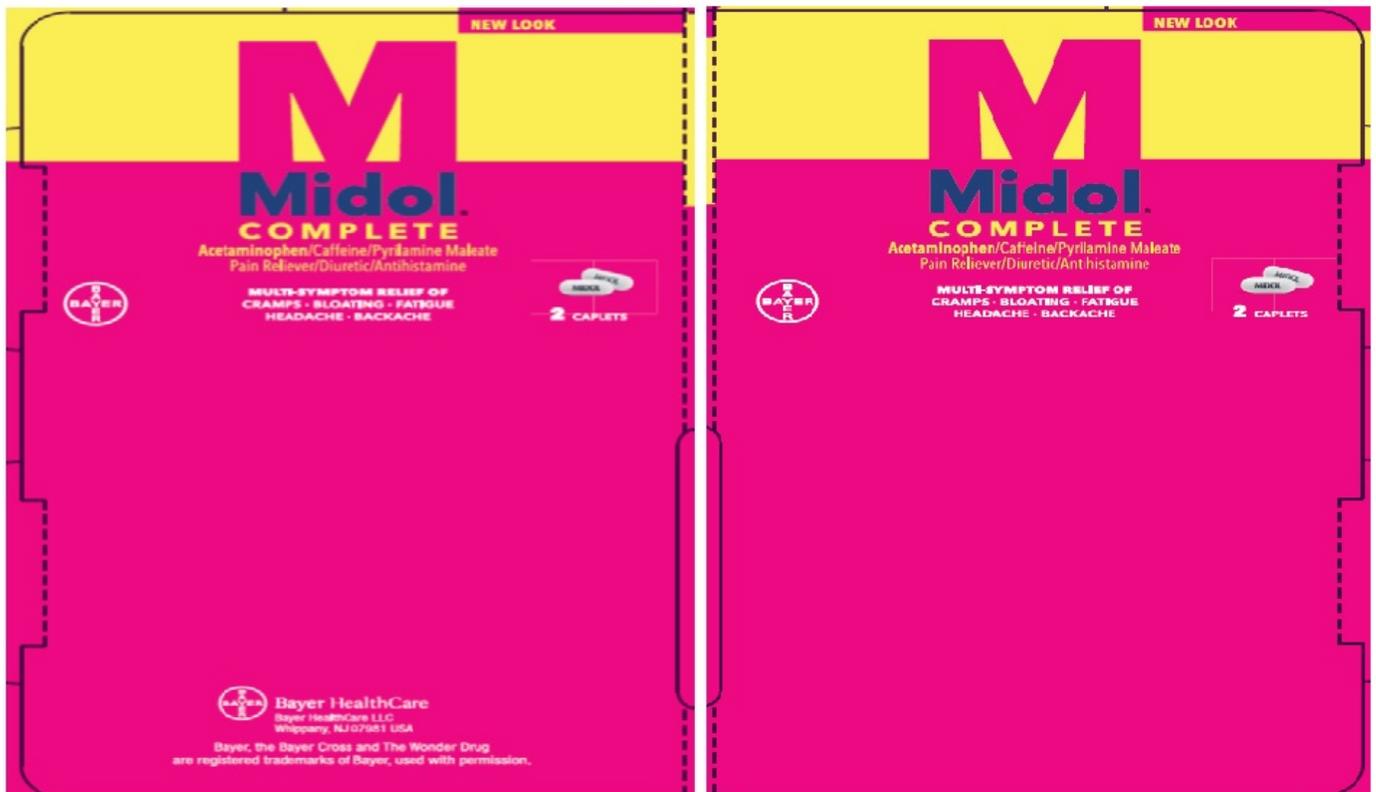
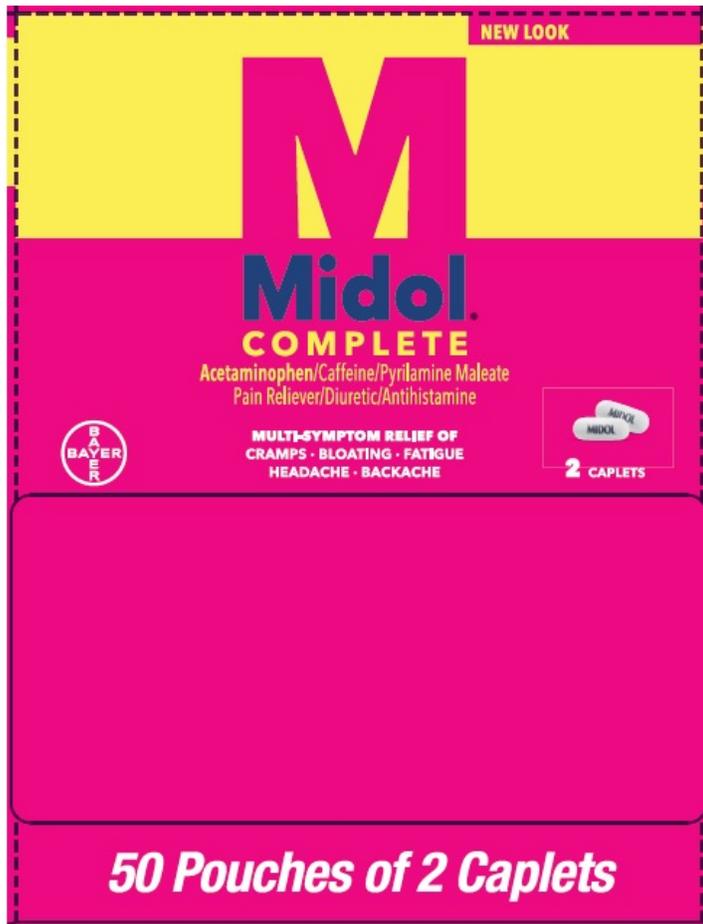
**Midol[®]
Complete**

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

**MAXIMUM STRENGTH
MULTI-SYMP TOM
RELIEF OF**

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

50 POUCHES of 2 CAPLETS





This product is repackaged by RJ General Corp, 2024 Northwest Dr., Cincinnati, Ohio 45231 (513)621-3738 (Mon-Fri 9AM-3PM EST) from a product manufactured by Bayer. Bayer®, the Bayer Cross® and The Wonder Drug are registered trademarks of Bayer, used with permission.

<p>Drug Facts</p> <p>Active ingredients (in each caplet) Acetaminophen 500 mg Pain reliever Durable Pyrimine 60 mg Antihistamine Pyrimine maleate 15 mg</p> <p>Purpose Ask a doctor before use if you have liver disease ● glucose ● difficulty in urination due to enlargement of the prostate gland ● a breathing problem such as emphysema or chronic bronchitis</p>	<p>Uses for the temporary relief of these symptoms ● associated with menstrual periods ● colds ● headache ● muscle aches ● fatigue</p> <p>Warnings Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take ● more than 8 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 Allergy Alert: acetaminophen may cause severe skin or severe allergic reactions. Symptoms may include ● skin redness ● hives ● rash ● fever ● facial swelling ● asthma (wheezing) ● hives ● If a skin or general allergic reaction occurs, stop use and seek medical help right away.</p> <p>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.</p> <p>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 8 caplets per day. ● children under 12 years: consult a doctor.</p> <p>propylparaben, polyethylene glycol, stearic acid, titanium dioxide, triacetin</p>
<p>Drug Facts (continued)</p> <p>Ask a doctor before use if you have</p>	<p>Other information ● Store at room temperature, avoid temperatures above 25°C (77°F).</p> <p>Inactive ingredients carnaub wax, croscarmellose sodium, FD&C Blue #2 aluminum lake, hypromellose, magnesium stearate, microcrystalline cellulose.</p> <p>Questions or comments? 1-800-331-4536 (Mon-Fri 9AM-5PM EST)</p>

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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
PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	15 mg
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	60 mg

Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I3O)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TRIACETIN (UNII: XHX3C3X673)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 2 (UNII: L06K8R7DQK)	
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	10/02/2014	
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 Drug	M013	02/10/2014	

Labeler - R J General Corporation (122542830)

Establishment

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