

**MIDOL COMPLETE- acetaminophen, caffeine, pyrilamine maleate tablet**  
**JC World Bell Wholesale Co., Inc.**

-----  
**MIDOL 2'S BLISTER PACK**

***Drug Facts***

***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
- muscle aches
- fatigue

***Warnings***

This product contains acetaminophen. Severe liver damage may occur if you take **Liver warning:**

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

- 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
  
- skin reddening
- blisters
- rash
- hives

- facial swelling
- asthma (wheezing)
- shock

**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)

## Package Labeling:



# MIDOL COMPLETE

acetaminophen, caffeine, pyrilamine maleate tablet

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:50269-009(NDC:0280-8005)
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)	CAFFEINE	60 mg
<b>PYRILAMINE MALEATE</b> (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL)	PYRILAMINE MALEATE	15 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 2--ALUMINUM LAKE</b> (UNII: 4AQJ3LG584)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>CELLULOSE, MICROCRYSTALLINE</b> (UNII: OP1R32D61U)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

## Product Characteristics

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

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50269-009-06	6 in 1 BOX	11/20/2019	
1		2 in 1 BLISTER PACK		
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	11/20/2019	
--------------------	------	------------	--

**Labeler -** JC World Bell Wholesale Co., Inc. (805257581)

**Establishment**

Name	Address	ID/FEI	Business Operations
JC World Bell Wholesale Co., Inc.		805257581	repack(50269-009)

Revised: 11/2023

JC World Bell Wholesale Co., Inc.