

**MIDOL COMPLETE GELCAPS- midol complete tablet, coated**  
**Bayer HealthCare LLC**

-----  
**Midol Complete Gelcaps**

**Drug Facts**

**Active ingredients (in each gelcap) Purpose**

**Acetaminophen 500 mg.....Pain reliever**

Caffeine 60 mg.....Diuretic

Pyrilamine maleate 15 mg.....Antihistamine

**Purpose**

**Uses** for the temporary relief of these symptoms associated with menstrual periods:

- cramps
- bloating
- water-weight gain
- headache
- backache
- muscle ache
- fatigue

**Warnings**

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

· more than 6 gelcaps 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

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 gelcaps with water
  - repeat every 6 hours, as needed
  - do not exceed 6 gelcaps per day
- children under 12 years: consult a doctor

Other information

- store at room temperature
- avoid excessive heat 104°F (40°C)



## MIDOL COMPLETE GELCAPS

midol complete tablet, coated

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-8015
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

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

### Inactive Ingredients

Ingredient Name	Strength
<b>D&amp;C RED NO. 33</b> (UNII: 9DBA0SBB0L)	
<b>ALUMINUM OXIDE</b> (UNII: LMI26O6933)	
<b>EDETATE DISODIUM</b> (UNII: 7FLD91C86K)	
<b>FERROSFERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>CROSCARMELOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>GLYCERIN</b> (UNII: PDC6A3C0OX)	

### Product Characteristics

<b>Color</b>	turquoise	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	MIDOL
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-8015-24	3 in 1 CARTON	12/15/2014	
1		24 in 1 BLISTER PACK; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M027	12/15/2014	

**Labeler** - Bayer HealthCare LLC (112117283)

Revised: 12/2025

Bayer HealthCare LLC