

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

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 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)

Inactive ingredients black iron oxide, carnauba wax, croscarmellose sodium, D&C red #33 aluminum lake, edetate disodium, FD&C blue #1 aluminum lake, gelatin, glycerin, hypromellose, lecithin, magnesium stearate, microcrystalline cellulose, pregelatinized starch, propylene glycol, shellac, simethicone, stearic acid, titanium dioxide, triacetin

Questions or comments? 1-800-331-4536 (Mon-Fri 9AM - 5PM EST)





1029832

Drug Facts (continued)
Other information ● store at room temperature ● avoid excessive heat (40°F (40°C))
Inactive ingredients black iron oxide, titanium dioxide, triacetin, glycol, shellac, simethicone, stearic acid, cellulose, pregelatinized starch, polyene lecithin, magnesium stearate, microcrystalline

EXPIRES

LOT & EXP

Midol Complete

Visit Midol.com

24 GELCAPS

Drug Facts (continued)
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
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 diseases ● 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 ● especially in children ● alcohol, sedatives, and ● avoid alcoholic drinks ● excitability may occur
When using this product ● you may get drowsy ● taking sedatives or tranquilizers ● avoid alcoholic drinks ● excitability may occur ● avoid alcoholic drinks ● excitability may occur ● avoid alcoholic drinks ● excitability may occur
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
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.
If pregnant or breast-feeding, ask a health professional before use.
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
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
When using this product ● you may get drowsy ● taking sedatives or tranquilizers ● avoid alcoholic drinks ● excitability may occur ● avoid alcoholic drinks ● excitability may occur ● avoid alcoholic drinks ● excitability may occur

Do not use if blister is cut or broken.
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 Morrisstown, NJ 07962-1910 USA
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2843

Midol Complete

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



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



24 GELCAPS

midol complete tablet, coated

Product Information

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

Active Ingredient/Active Moiety

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

Inactive Ingredients

Ingredient Name	Strength
D&C RED NO. 33 (UNII: 9DBA0SBB0L)	
ALUMINUM OXIDE (UNII: LM26O6933)	
EDETATE DISODIUM (UNII: 7FLD91C86K)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
GLYCERIN (UNII: PDC6A3C0OX)	

Product Characteristics

Color	turquoise	Score	no score
Shape	OVAL	Size	10mm
Flavor		Imprint Code	MIDOL
Contains			

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 not final	part343	12/15/2014	

Labeler - Bayer HealthCare LLC (112117283)

