

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)

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)



MIDOL COMPLETE 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: LMI26O6933) | |
| EDETATE DISODIUM (UNII: 7FLD91C86K) | |
| FERROSFERRIC OXIDE (UNII: XM0M87F357) | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| CROSCARMELOSE 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 Drug | M027 | 12/15/2014 | |

Labeler - Bayer HealthCare LLC (112117283)

Revised: 11/2023

Bayer HealthCare LLC