

MIDOL COMPLETE- acetaminophen, caffeine, and pyrilamine maleate tablet Lil' Drug Store Products, Inc

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

Drug Facts

| Active ingredients (in each caplet) | Purpose |
|--|----------------|
| 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

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) or www.midol.com

PRINCIPAL DISPLAY PANEL - 4 Caplet Pouch Carton

Midol[®]
COMPLETE

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

BAYER

MULTI-SYMPTOM RELIEF OF
CRAMPS • BLOATING • FATIGUE
HEADACHE • BACKACHE

4
Caplets

Lil' Drug Store[®]



Drug Facts (continued)

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- If you have ever had an allergic reaction to this product or any of its ingredients

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| MIDOL COMPLETE | | | |
|---|----------------|---------------------------|-----------------|
| acetaminophen, caffeine, and pyrilamine maleate tablet | | | |
| Product Information | | | |
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:66715-9745 |
| Route of Administration | ORAL | | |
| Active Ingredient/Active Moiety | | | |
| Ingredient Name | | Basis of Strength | Strength |
| ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D) | | ACETAMINOPHEN | 500 mg |
| CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) | | CAFFEINE | 60 mg |
| PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL) | | PYRILAMINE MALEATE | 15 mg |

Inactive Ingredients

| Ingredient Name | Strength |
|--|----------|
| CARNAUBA WAX (UNII: R12CBM0EIZ) | |
| CROSCARMELOSE SODIUM (UNII: M28OL1HH48) | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | |
| STARCH, CORN (UNII: O8232NY3SJ) | |
| PROPYLENE GLYCOL (UNII: 6DC9Q167V3) | |
| SHELLAC (UNII: 46N107B710) | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | |
| TRIACETIN (UNII: XHX3C3X673) | |

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:66715-9745-2 | 2 in 1 CARTON | 12/01/2011 | |
| 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 not final | part343 | 12/01/2011 | |

Labeler - Lil' Drug Store Products, Inc (093103646)

Revised: 7/2021

Lil' Drug Store Products, Inc