

MIDOL COMPLETE- acetaminophen, caffeine, and pyrilamine maleate tablet **Select Corporation**

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
- fatigue
- backache
- muscle aches

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

- take 2 caplets with water
- repeat every 6 hours, as needed

| | |
|-----------------------------|---------------------------------------------------------------------------------|
| children 12 years and older | <ul style="list-style-type: none">do not exceed 6 caplets per day |
| children under 12 years | consult a doctor |

Other information

- store at room temperature. Avoid temperatures above 25°C (77°F).

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 9-5 EST)

PRINCIPAL DISPLAY PANEL - 2 Caplet Pouch Blister Pack

Midol[®]
COMPLETE


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

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

NEW LOOK

2 Caplets
Single-Pack

Do not use if pouch is torn or open.





Bayer HealthCare LLC
Whippany, NJ 07981

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Bayer


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Midol COMPLETE
Acetaminophen/Caffeine/Pyrimamine Maleate
Pain Reliever/Diuretic/Antihistamine

NEW LOOK
2 Caplets
Single-Pack

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



Open Flap for **DRUG FACTS** →

READ THE LABEL
Read all warnings and directions before use

Midol COMPLETE
Acetaminophen/Caffeine/Pyrimamine Maleate
Pain Reliever/Diuretic/Antihistamine

NEW LOOK



6 55708 11841 2

Single - Pack: 2 Caplets

This Product is repackaged by:
Select Corporation 1433 Walnutwright Way, Carrollton, TX 75007
877-244-4400 M - F 9am - 5pm, from a product manufactured by Bayer.

Drug Facts

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Caffeine 80 mg.....Diuretic
Pyrimamine maleate 15 mg.....Antihistamine

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• fatigue • backache • muscle aches

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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.
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Drug Facts (continued)

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Drug Facts (continued)

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

2811841056

MIDOL COMPLETE

acetaminophen, caffeine, and pyrimamine maleate tablet

Product Information

| | | | |
|--------------------------------|----------------|---------------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:52904-841(NDC:0280-8005) |
| Route of Administration | ORAL | | |

Active Ingredient/Active Moiety

| Ingredient Name | Basis of Strength | Strength |
|-----------------|-------------------|----------|
|-----------------|-------------------|----------|

| | | |
|-----------------------------------------------------------------------------|--------------------|--------|
| acetaminophen (UNII: 36209ITL9D) (acetaminophen - UNII:36209ITL9D) | 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) | |
| croscarmellose sodium (UNII: M28OL1HH48) | |
| FD&C blue no. 2 (UNII: L06K8R7DQK) | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | |
| magnesium stearate (UNII: 70097M6I30) | |
| microcrystalline cellulose (UNII: OP1R32D61U) | |
| propylene glycol (UNII: 6DC9Q167V3) | |
| shellac (UNII: 46N107B710) | |
| titanium dioxide (UNII: 15FIX9V2JP) | |
| triacetin (UNII: XHX3C3X673) | |

Product Characteristics

| | | | |
|-----------------|---------------|---------------------|----------|
| Color | WHITE | Score | no score |
| Shape | OVAL (oblong) | Size | 17mm |
| Flavor | | Imprint Code | MIDOL |
| Contains | | | |

Packaging

| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
|---|------------------|-------------------------------------------------|----------------------|--------------------|
| 1 | NDC:52904-841-04 | 1 in 1 BLISTER PACK | 02/10/2014 | |
| 1 | | 2 in 1 POUCH; Type 0: Not a Combination Product | | |
| 2 | NDC:52904-841-20 | 20 in 1 CARTON | 02/10/2014 | |
| 2 | | 2 in 1 POUCH; Type 0: Not a Combination Product | | |
| 3 | NDC:52904-841-25 | 25 in 1 CARTON | 02/10/2014 | |
| 3 | | 2 in 1 POUCH; Type 0: Not a Combination Product | | |
| 4 | NDC:52904-841-30 | 30 in 1 CARTON | 02/10/2014 | |
| 4 | | 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 | 02/10/2014 | |

Labeler - Select Corporation (053805599)

Revised: 4/2022

Select Corporation