MIDOL COMPLETE- acetaminophen, caffeine, and pyrilamine maleate tablet R J General Corporation

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
- fatique

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.

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.

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.

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 9AM - 5PM EST)

PRINCIPAL DISPLAY PANEL - 100 Caplet Pouch Carton

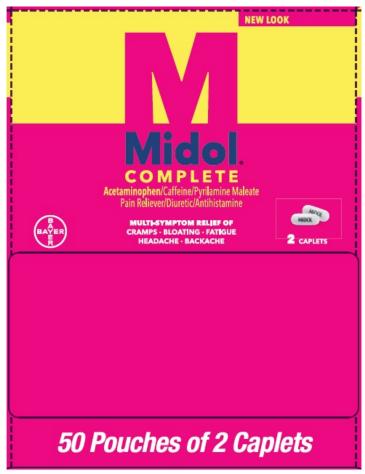
Midol_® Complete

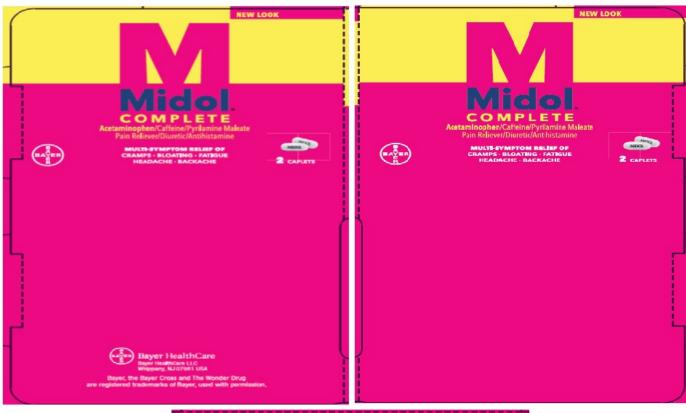
Acetaminophen/Caffeine/Pyrilamine Maleate Pain Reliever/Diuretic/Antihistamine

MAXIMUM STRENGTH MULTI-SYMPTOM RELIEF OF

CRAMPS, BLOATING FATIGUE, BACKACHE & HEADACHE

50 POUCHES of 2 CAPLETS







MIDOL COMPLETE

acetaminophen, caffeine, and pyrilamine maleate tablet

| Product Information | | | |
|-------------------------|----------------|--------------------|------------------------------|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:70264-012(NDC:0280-8005) |
| Route of Administration | ORAL | | |

| Active Ingredient/Active Moiety | | | | |
|--|--------------------------|----------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| PYRILAMINE MALEATE (UNII: R35D29L3ZA) (PYRILAMINE - UNII:HPE317O9TL) | PYRILAMINE MALEATE | 15 mg | | |
| ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) | ACETAMINOPHEN | 500 mg | | |
| CAFFEINE (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E) | CAFFEINE | 60 mg | | |
| | | | | |

| Inactive Ingredients | | | | |
|---|----------|--|--|--|
| Ingredient Name | Strength | | | |
| HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO) | | | | |
| MAGNESIUM STEARATE (UNII: 70097M6I30) | | | | |
| MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U) | | | | |
| POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A) | | | | |
| TRIACETIN (UNII: XHX3C3X673) | | | | |
| CARNAUBA WAX (UNII: R12CBM0EIZ) | | | | |
| TITANIUM DIOXIDE (UNII: 15FIX9V2JP) | | | | |
| CROSCARMELLOSE SODIUM (UNII: M280L1HH48) | | | | |
| FD&C BLUE NO. 2 (UNII: L06K8R7DQK) | | | | |
| SHELLAC (UNII: 46N107B710) | | | | |

| Product Characteristics | | | |
|-------------------------|-------|--------------|----------|
| Color | white | Score | no score |
| Shape | OVAL | Size | 17mm |
| Flavor | | Imprint Code | MIDOL |
| Contains | | | |

| P | Packaging | | | | |
|---|----------------------|---|-------------------------|-----------------------|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | |
| 1 | NDC:70264-012- 01 | 50 in 1 CARTON | 10/02/2014 | | |
| 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 Drug | M013 | 02/10/2014 | | |
| | | | | |

Labeler - R J General Corporation (122542830)

| Establishment | | | | |
|-------------------------|---------|-----------|----------------------------|--|
| Name | Address | ID/FEI | Business Operations | |
| R J General Corporation | | 122542830 | repack(70264-012) | |