

MIDOL- acetaminophen, caffeine, and pyrilamine maleate tablet
Navajo Manufacturing Company Inc.

Midol

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 500 mg

Caffeine 60 mg

Pyrilamine maleate 15 mg

Purpose

Pain reliever

Diuretic

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. Avoid excessive heat above 40°C (104°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?

1-800-331-4536 (Mon-Fri 9AM - 5PM EST) or www.midol.com

Principal Display Panel



MIDOL			
acetaminophen, caffeine, and pyrilamine maleate tablet			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:67751-145(NDC:0280-8005)
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)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
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:67751-145-01	2 in 1 CARTON	09/19/2016	
1		2 in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:67751-145-02	2 in 1 CARTON	09/19/2016	
2		4 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	09/19/2016	

Labeler - Navajo Manufacturing Company Inc. (091917799)

Establishment			
Name	Address	ID/FEI	Business Operations
Navajo Manufacturing Company Inc.		136941411	relabel(67751-145) , repack(67751-145)