

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

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**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).

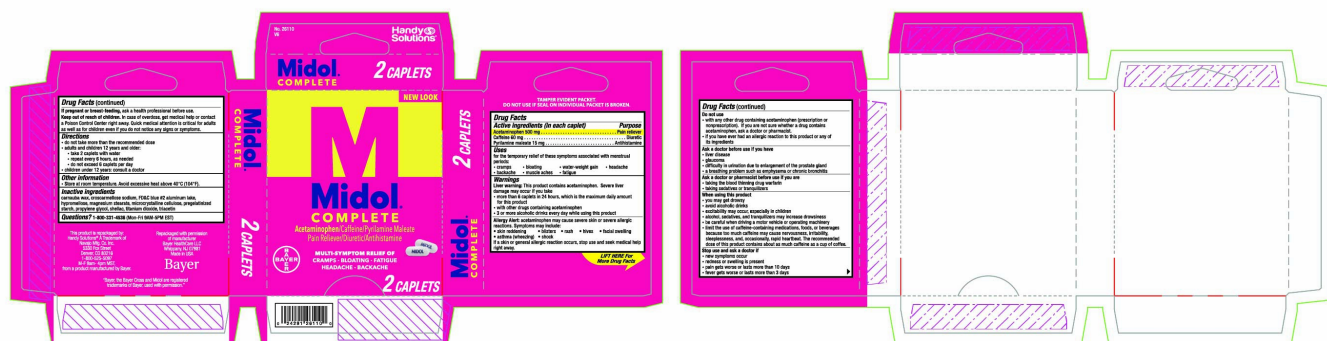
### Inactive ingredients

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](http://www.midol.com)

### Principal Display Panel



<b>MIDOL</b>			
acetaminophen, caffeine, and pyrilamine maleate tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:67751-145(NDC:0280-8005)
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)		ACETAMINOPHEN	500 mg
<b>CAFFEINE</b> (UNII: 3G6A5W338E) (CAFFEINE - UNII:3G6A5W338E)		CAFFEINE	60 mg
<b>PYRILAMINE MALEATE</b> (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: 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: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)