

**MIDOL LONG LASTING RELIEF- acetaminophen tablet, extended release**  
**Bayer HealthCare LLC.**

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**Midol Long Lasting Relief**

***Drug Facts***

**Active ingredients (in each caplet)**

Acetaminophen 650 mg

***Purpose***

Pain reliever/fever reducer

**Uses**

***Uses***

- Temporarily relieves minor aches and pains due

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- muscular aches
  - backache
  - minor pain of arthritis
  - toothache
  - premenstrual and menstrual cramps
  - headache
  - the common cold
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- temporarily reduces fever

***Warnings***

**Liver warning:** The product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Allergy Alert:** Acetaminophen may cause severe skin reactions.

Symptoms may include:

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- skin reddening
  - blisters
  - rash
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- If a skin 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 are not sure whether a drug contains acetaminophen, ask a doctor

or pharmacist.

- If you are allergic to acetaminophen or any of the inactive ingredients in this product.

**Ask a doctor before use** if you have liver disease

**As a doctor or pharmacist before use** if you are taking the blood thinning drug warfarin.

Stop use and ask a doctor if

- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- new symptoms occur
- redness or swelling is present

These could be signs of a serious condition

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

## Directions

### Directions

- do not take more than directed (see overdose warning)

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adults and children 12 years and over

- take 2 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 caplets in 24 hours
  - do not use for more than 10 days unless directed by a doctor

children under 12 years

- do not use
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## Other information

### Other information

- store at 20-25° (68-77°F). Avoid excessive heat 40°C (104°F).
- **do not use if printed foil under cap is broken or missing**

**Inactive ingredients** carnauba wax, colloidal silicon dioxide, croscarmellose sodium, hypromellose, magnesium stearate, maltodextrin, microcrystalline cellulose, polyethylene glycol polysorbate 80, povidone, pregelatinized starch, stearic acid, titanium dioxide

## Questions or comments

**Questions or comments?** 1-800-331-4536



## MIDOL LONG LASTING RELIEF

acetaminophen tablet, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:0280-8090
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	<b>ACETAMINOPHEN</b>	650 mg
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### Inactive Ingredients

Ingredient Name	Strength
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>CROSCARMELLOSE SODIUM</b> (UNII: M28OL1HH48)	
<b>MALTODEXTRIN</b> (UNII: 7CVR7L4A2D)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>POLYSORBATE 80</b> (UNII: 6OZP39ZG8H)	
<b>POVIDONE</b> (UNII: FZ989GH94E)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	OVAL	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	MLLR
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0280-8090-20	1 in 1 CARTON	03/10/2017	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075077	03/10/2017	

**Labeler** - Bayer HealthCare LLC. (112117283)