

**ACETAMINOPHEN- acetaminophen tablet**  
**Marlex Pharmaceuticals Inc**

*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.*

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**Acetaminophen**

***Drug Facts***

***Active Ingredient***

***(in each tablet)***

*Acetaminophen USP 500 mg*

***Purpose***

*Pain Reliever/Fever Reducer*

***Uses***

Temporary relieves minor aches and pains due to:

- The common cold
- Headache
- Backache
- Minor pain of arthritis
- Toothache
- Muscular aches
- Premenstrual and menstrual cramps

\* Temporarily reduces fever

**Warnings**

**Liver warning:** this product contains acetaminophen. The maximum daily dose of this product is 6 tablets (3,000 mg) in 24 hours. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**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 allergic to acetaminophen or any of the inactive ingredients in this product.

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

liver disease.

**Ask 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:**

Taking more than the recommended dose (overdose) may cause liver damage. 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**

**Do not take more than directed (see overdose warning)**

**Adults and Children 12 years and over:**

- Take 2 tablets every 6 hours while symptoms last.
- Do not take more than 6 tablets in 24 hours, unless directed by a doctor.
- Do not use for more than 10 days unless directed by a doctor.

**Children under 12 years:**

- ask a doctor.

**Other Information**

- Store between 20-25 °C (68-77 °F).
- See end panel for lot number and expiration date.

**Inactive Ingredients**

Povidone, Pregelatinized Starch, Sodium Carboxymethyl Starch, Stearic Acid

**Distributed by:**

Marlex Pharmaceuticals, Inc.  
New Castle, DE 19720

**Principal Display Panel**

**NDC 10135-152-01**  
**ACETAMINOPHEN**  
**500 MG**

NDC 10135-0152-01

# ACETAMINOPHEN

## 500 mg

Compare to  
Extra Strength **TYLENOL** <sup>(S)</sup>  
active ingredient \*

DO NOT USE IF IMPRINTED SAFETY SEAL  
UNDER CAP IS BROKEN OR MISSING.

**100 TABLETS**



\*This product is not manufactured or distributed by McNeil Consumer Products Company. Marlex Pharmaceuticals is not affiliated with the owner of the Trademark Extra Strength Tylenol ®.



<b>Drug Facts</b>	
<b>Active Ingredient</b> (in each tablet) Acetaminophen USP 500 mg	<b>Purpose</b> Pain Reliever/ Fever Reducer
<b>Uses</b> Temporary relieves minor aches and pains due to:	
<ul style="list-style-type: none"> <li>• The common cold</li> <li>• Headache</li> <li>• Backache</li> <li>• Minor pain of arthritis</li> <li>• Toothache</li> <li>• Muscular aches</li> <li>• Premenstrual and menstrual cramps</li> </ul>	
* Temporarily reduces fever.	
<b>Warnings</b>	
<b>Liver warning:</b> this product contains acetaminophen. The maximum daily dose of this product is 6 tablets (3,000 mg) in 24 hours. Severe liver damage may occur if you take	
<ul style="list-style-type: none"> <li>• more than 4,000 mg of acetaminophen in 24 hours</li> <li>• with other drugs containing acetaminophen</li> <li>• 3 or more alcoholic drinks every day while using this product</li> </ul>	
<b>Do not use</b>	
<ul style="list-style-type: none"> <li>• with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.</li> <li>• if you are allergic to acetaminophen or any of the inactive ingredients in this product.</li> </ul>	

REV 04/18 HP  
**Drug Facts** (continued on back)

ACTUAL SIZE • DIE LINE DOES NOT PRINT

<b>Drug Facts</b> (continued)
<b>Ask a doctor before use if you have liver disease.</b>
<b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b>
<b>Stop use and ask a doctor if</b>
<ul style="list-style-type: none"> <li>• Pain gets worse or lasts more than 10 days.</li> <li>• Fever gets worse or lasts more than 3 days.</li> <li>• New symptoms occur.</li> <li>• Redness or swelling is present.</li> </ul>
These could be signs of a serious condition.
<b>If pregnant or breast-feeding,</b> ask a health professional before use.
<b>Keep out of reach of children.</b>
<b>Overdose warning:</b> Taking more than the recommended dose (overdose) may cause liver damage. 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.
<b>Directions</b> Do not take more than directed (see overdose warning)
<b>Adults and Children 12 years and over:</b>
<ul style="list-style-type: none"> <li>• Take 2 tablets every 6 hours while symptoms last.</li> <li>• Do not take more than 6 tablets in 24 hours, unless directed by a doctor.</li> <li>• Do not use for more than 10 days unless directed by a doctor.</li> </ul>
<b>Children under 12 years:</b>
• ask a doctor.
<b>Other Information</b>
<ul style="list-style-type: none"> <li>• store between 20-25°C (68-77°F).</li> <li>• see end panel for lot number and expiration date.</li> </ul>
<b>Inactive Ingredients</b>
Pregelatinized Starch, Povidone, Stearic Acid, Sodium Carboxymethyl Starch.
<b>Distributed by:</b>
Marlex Pharmaceuticals, Inc. New Castle, DE 19720

## ACETAMINOPHEN

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10 135-152
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

### Inactive Ingredients

Ingredient Name	Strength
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM (UNII: K679OBS311)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND	<b>Size</b>	12mm
<b>Flavor</b>		<b>Imprint Code</b>	MLX;152
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10 135-152-01	100 in 1 BOTTLE; Type 0: Not a Combination Product	01/01/1997	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	01/01/1997	

**Labeler** - Marlex Pharmaceuticals Inc (782540215)

Revised: 2/2021

Marlex Pharmaceuticals Inc