

**ACETAMINOPHEN- acetaminophen tablet**  
**Cispharma, 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 TABLETS, 500 mg**

**Drug Facts**

**Active ingredient (in each tablet)**

Acetaminophen ..... 500 mg

Pain Reliever/ Fever Reducer

**Uses**

Temporarily relieves minor aches and pains due to:

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

temporarily reduces fever

**Warnings**

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers or fever reducers. Acetaminophen may cause liver damage.

**Do not use** with any other drug containing acetaminophen

**Stop use and ask a doctor if**

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

These could be signs of a serious condition.

Indicated for pain relief.

**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)**

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- |                                       |  |
|---------------------------------------|--|
| adults and children 12 years and over | <ul style="list-style-type: none"><li>• take 2 tablets every 4 to 6 hours while symptoms last</li><li>• if needed, tablets may be crushed and should be taken immediately. Take the entire dose for best results. Crushing the tablets will result in bitter taste.</li><li>• do not take more than 8 tablets in 24 hours</li><li>• do not use more than 10 days unless directed by a doctor</li></ul> |
| children under 12 years               | <ul style="list-style-type: none"><li>• do not use this adult product in children under 12 years of age: this will provide more than the recommended dose (overdose) and may cause liver damage.</li></ul>   |
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**Other Information**

- store between 20°- 25°C (68°- 77°F)
- **do not use if the box is**

**Inactive Ingredients**

povidone, pregelatinized starch, stearic acid

\*This product is not manufactured or distributed by McNeil Consumer & Specialty Pharmaceuticals, distributor of Tylenol®

**Questions or Comments?**

**Call 1-866-383-9908**

**Manufactured by:**

**Cispharma Inc  
1212 Cranbury S River Road  
Cranbury, NJ 08512**



# ACETAMINOPHEN TABLETS, 500 MG

**Pain Reliever  
Fever Reducer**

**NDC number 52204-114-99**

**Contains No Aspirin**

**Compare to the active ingredient in Tylenol®\***

### Drug Facts

**Active ingredient (in each tablet) Purpose**  
Acetaminophen 500 mg..... Pain reliever/ fever reducer

### Uses

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

### Warnings

**Alcohol warning:** If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take acetaminophen or other pain relievers or fever reducers. Acetaminophen may cause liver damage.

Do not use with any other drug containing acetaminophen

### Stop use and ask a doctor if

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  - new symptoms occur
  - redness or swelling is present
- These could be signs of a serious condition.

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**Keep out of reach of children.**

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### Directions: do not take more than directed (see overdose warning)

adults and children 12 years and over	<ul style="list-style-type: none"> <li>take 2 tablets every 4 to 6 hours while symptoms last</li> <li>if needed, tablets may be crushed and should be taken immediately. Take the entire dose for best results. Crushing the tablets will result in bitter taste.</li> <li>do not take more than 8 tablets in 24 hours</li> <li>do not use more than 10 days unless directed by a doctor</li> </ul>
children under 12 years	<ul style="list-style-type: none"> <li>do not use this adult product in children under 12 years of age; this will provide more than the recommended dose (overdose) and may cause liver damage.</li> </ul>

### Other information

- store between 20°- 25°C (68°- 77°F)
- do not use if the box is opened

### Inactive ingredients

povidone, pregelatinized starch, stearic acid

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### Questions or Comments?

Call 1-866-383-9908

### Manufactured by:

Cispharma Inc  
1212 Cranbury S River Road  
Cranbury, NJ 08512

**Batch:**                      **Exp:**

Gross wt:      Tare wt:      Net wt:

**Total No. of tablets:**

## ACETAMINOPHEN

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:52204-114
<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)	
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	

### Product Characteristics

<b>Color</b>	WHITE (White)	<b>Score</b>	2 pieces
<b>Shape</b>	ROUND (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:52204-114-99	35587 in 1 DRUM		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph not final	part343	03/28/2011	

**Labeler** - Cispharma, Inc (833171445)

**Registrant** - Cispharma, Inc (833171445)

### Establishment

Name	Address	ID/FEI	Business Operations
Cispharma, Inc		833171445	manufacture

Revised: 3/2011

Cispharma, Inc