

**EXTRA STRENGTH ACETAMINOPHEN- acetaminophen tablet**  
**Health Pharma USA LLC**

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**Acetaminophen Extra Strength 500 mg**

**Active Ingredient**

**(in each tablet)**

Acetaminophen 500mg

**Purpose**

Pain reliever/fever reducer

**Uses**

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

**Warnings**

**Liver warning:** This product contains acetaminophen. 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

**Allergy alert:** Acetaminophen may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

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 have ever had an allergic reaction to this product or any of its ingredients

**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 (1-800-222-1222) right away. Quick medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

**Do not exceed recommended dosage.**

**Directions**

- do not use more than directed (**see overdose warning**)
- Adults and children 12 years of age and older:
  - Take 2 caplets every 6 hours while symptoms last.
  - Do not take more than 6 caplets in 24 hours, unless directed by a doctor
  - Do not use more than 10 days unless directed by a doctor.
- Children under 12 years of age: Do not use this extra strength product. This will provide more than the recommended dose (overdose) and could cause serious health problems.

**Other Information**

- store at controlled room temperature 20-25°C (68-77°F).
- read all product information before using.
- TAMPER EVIDENT: DO NOT USE IF IMPRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

**Inactive Ingredients**

Hypromellose, Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch, Polyethylene Glycol, Polyvinyl Pyrolidone, Stearic Acid, Talc, Titanium Dioxide

## Questions or Comments

1-844-832-1138 (Mon-Fri 9AM-5PM EST) or [www.healthlifeofusa.com](http://www.healthlifeofusa.com)

### PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

\* This product is not manufactured or distributed by McNeil-Consumer Healthcare, owner of the registered trademark Tylenol\*.



**Health Pharma USA LLC**

1600 Hart Street, Rahway, NJ 07065

Phone: 732-540-8421

**BULK LABEL \_\_\_\_\_ of \_\_\_\_\_**

**PRODUCT NAME: Acetaminophen 500 mg Tablet**

**PRODUCT CODE # PC031**

**LOT #**

**Labeler code – 71679-031-00**

**NET WEIGHT (KG)**

**Caplets/BOX**

**16.00**

**29,090 Tablet**

**WARNING:** Keep out of Children. This bulk shipment is intended for further processing only. Repackage contents as soon as possible. This is a shipping container only and will not protect contents from damage by heat, cold and moisture indefinitely. Manufacturer will not accept responsibility for spoilage or violations of the food, Drug and cosmetic act due to prolonged storage in this container. Contents must be repackaged prior to resale and must be labeled in full compliance with the requirement of the Food, Drug and Cosmetic Act.

**STORAGE:** Store at a controlled room temperature 15-30°C (59-86° F)

## EXTRA STRENGTH ACETAMINOPHEN

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:71679-031
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

### Inactive Ingredients

<b>Ingredient Name</b>	<b>Strength</b>
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<b>STARCH, PREGELATINIZED CORN</b> (UNII: O8232NY3SJ)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>CARBOXYMETHYLCELLULOSE SODIUM, UNSPECIFIED FORM</b> (UNII: K679OBS311)	
<b>HYPROMELLOSES</b> (UNII: 3NXW29V3WO)	
<b>CARNAUBA WAX</b> (UNII: R12CBM0EIZ)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>MINERAL OIL</b> (UNII: T5L8T28FGP)	

### Product Characteristics

<b>Color</b>	white	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	18mm
<b>Flavor</b>		<b>Imprint Code</b>	AP500
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:71679-031-00	1 in 1 BOX	07/31/2017	
1		29090 in 1 BAG; 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	07/31/2017	

**Labeler** - Health Pharma USA LLC (080804485)

### Establishment

Name	Address	ID/FEI	Business Operations
Health Pharma USA LLC		080804485	manufacture(71679-031)

Revised: 10/2023

Health Pharma USA LLC