

**ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet**  
**Aurohealth LLC**

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***Drug Facts***

***Active ingredient (in each caplet)***

Acetaminophen USP 500 mg

***Purpose***

Pain reliever/fever reducer

***Uses***

- temporarily 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.

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 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:**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 | <ul style="list-style-type: none"><li>• take 2 caplets every 6 hours while symptoms last</li><li>• do not take more than 6 caplets 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> |
| children under 12 years               | ask a doctor   |

***Other information***

- store between 20° to 25°C (68° to 77°F)
- **do not use if printed foil seal under cap is torn or missing.**

***Inactive ingredients***

povidone, pregelatinized starch (maize), stearic acid.

***Questions or comments?***

call **1-855-274-4122**

Distributed by:

**AUROHEALTH LLC.**

279 Princeton- Hightstown Road,  
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/16/2014

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg (750 Caplets Bottle)**

**NDC 58602-776-88 Primary Health**

**Compare to the active ingredient in  
Tylenol<sup>®</sup> Extra strength Caplets \***

**See New Warnings Information & Directions**

**EXTRA STRENGTH**

**For Adults**

**Pain Relief**

**Acetaminophen Caplets 500 mg**

**Pain reliever/Fever reducer**

**N 79**

**750 CAPLETS**

**500 mg each**

**Drug Facts** (continued)

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)  
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**Other information** ■ store between 20° to 25°C (68° to 77°F)  
 ■ do not use if printed foil seal under cap is torn or missing.

**Inactive ingredients** povidone, pregelatinized starch (maize), stearic acid.

**Questions or comments?** call 1-855-274-4122

\*This product is not manufactured or distributed by McNeil consumer healthcare, distributor of Tylenol® Extra strength Caplets.

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**AUROHEALTH LLC**  
 279 Princeton-Hightstown Road  
 East Windsor, NJ 08520

Made in India Code: TS/DRUGS/16/2014

Contains No Aspirin

NDC 58602-776-88

**PH** PrimaryHealth

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

**Drug Facts**

| Active ingredient (in each caplet) | Purpose                     |
|------------------------------------|-----------------------------|
| Acetaminophen USP 500 mg.....      | Pain reliever/fever reducer |

**Uses**

temporarily 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**

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- 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 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



P1430863 LM-4953

NVZ

Compare to the active ingredient in Tylenol® Extra strength Caplets\*  
 See New Warnings Information & Directions  
**EXTRA STRENGTH**  
 For Adults

**Pain Relief**  
**ACETAMINOPHEN Caplets 500 mg**

Pain Reliever/Fever Reducer



750 CAPLETS  
 500 mg each

# ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet

## Product Information

|                                |                |                           |               |
|--------------------------------|----------------|---------------------------|---------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:58602-776 |
| <b>Route of Administration</b> | ORAL           |                           |               |

## Active Ingredient/Active Moiety

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

## Inactive Ingredients

| Ingredient Name                               | Strength |
|---|----------|
| <b>POVIDONE K30</b> (UNII: U725QWY32X)        |          |
| <b>STARCH, CORN</b> (UNII: O8232NY3SJ)        |          |
| <b>PALMITOSTEARIC ACID</b> (UNII: Q8Y7S3B85M) |          |

## Product Characteristics

|                 |                            |                     |          |
|-----------------|----------------------------|---------------------|----------|
| <b>Color</b>    | white (White to off White) | <b>Score</b>        | no score |
| <b>Shape</b>    | CAPSULE (Biconvex)         | <b>Size</b>         | 18mm     |
| <b>Flavor</b>   |                            | <b>Imprint Code</b> | N79      |
| <b>Contains</b> |                            |                     |          |

## Packaging

| # | Item Code      | Package Description                        | Marketing Start Date | Marketing End Date |
|---|----------------|--|----------------------|--------------------|
| 1 | NDC:58602-776- | 750 in 1 BOTTLE; Type 0: Not a Combination | 08/02/2022           |                    |

| 88                           | Product                                  | 09/02/2022           |                    |
|------------------------------|--|----------------------|--------------------|
| <b>Marketing Information</b> |  |                      |                    |
| Marketing Category           | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| OTC Monograph Drug           | M013                                     | 09/02/2022           |                    |

**Labeler** - Aurohealth LLC (078728447)

**Establishment**

| Name                   | Address | ID/FEI    | Business Operations                          |
|------------------------|---------|-----------|--|
| APL HEALTHCARE LIMITED |         | 650844777 | analysis(58602-776) , manufacture(58602-776) |

Revised: 11/2023

Aurohealth LLC