

**ACETAMINOPHEN- acetaminophen tablet**  
**Preferred Pharmaceuticals Inc.**

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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></ul> |
|---------------------------------------|---|

|                         |  |
|-------------------------|--|
|                         | <ul style="list-style-type: none"><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

Relabeled By: Preferred Pharmaceuticals Inc.

### **PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg (100 Caplets Bottle)**

#### **AUROHEALTH**

#### **NDC 68788-8559-1**

**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**

#### **100 Caplets**

#### **500 mg each**

# Extra Strength APAP Tab 500mg

Generic for Tylenol

Each tablet contains: Acetaminophen 500mg

**Pkg Size:** Exp Date:

Lot#:

Batch#:

Ins:

Mfg: Aurohealth LLC

Prod#:

Warning

Liver Warning: this product contains acetaminophen. The maximum daily dose of this product is 6 tablets (3,000mg). Severe liver damage may occur if you take more than 4,000mg of acetaminophen in 24 hours, with other drugs containing acetaminophen, 3 or more alcoholic drinks every day while using this product. Ask a doctor before use if you have liver disease or are taking the blood thinning drug warfarin. Do not use with any other drug containing acetaminophen. Store at 20°- 25°C (68°- 77°F). Keep out of the reach of children. Tablet is oval, white, and imprinted with N79



CAUTION: Federal law PROHIBITS transfer of this drug to any person other than the patient for whom it was prescribed



Directions English

Take \_\_\_ tablet(s)  
every \_\_\_ hours.

Instrucciones Espanol:

Toma \_\_\_ tableta(s)  
cada \_\_\_ horas.

Extra Strength APAP Tab 500mg

Qty: Ins:

Lot#: Bat#:

Prod# (NDC):

Extra Strength APAP Tab 500mg

Qty: Ins:

Lot#: Bat#:

Prod# (NDC):

Extra Strength APAP Tab 500mg

Qty:

Insurance NDC:

Lot#: Bat#:

Extra Strength APAP Tab 500mg

Qty: Ins:

Lot#: Bat#:

Prod# (NDC):

Log

Chart

Billing

Patient

## ACETAMINOPHEN

acetaminophen tablet

### Product Information

|                                |                |                           |                               |
|--------------------------------|----------------|---------------------------|-------------------------------|
| <b>Product Type</b>            | HUMAN OTC DRUG | <b>Item Code (Source)</b> | NDC:68788-8559(NDC:58602-773) |
| <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 K30 (UNII: U725QWY32X)        |          |
| STARCH, CORN (UNII: O8232NY35J)        |          |
| PALMITOSTEARIC ACID (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:68788-8559-1 | 100 in 1 BOTTLE; Type 0: Not a Combination Product | 01/08/2024           |                    |

## Marketing Information

| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
|--------------------|--|----------------------|--------------------|
| OTC Monograph Drug | M013                                     | 01/08/2024           |                    |

**Labeler** - Preferred Pharmaceuticals Inc. (791119022)

**Registrant** - Preferred Pharmaceuticals Inc. (791119022)

## Establishment

| Name                           | Address | ID/FEI    | Business Operations |
|--------------------------------|---------|-----------|---------------------|
| Preferred Pharmaceuticals Inc. |         | 791119022 | RELABEL(68788-8559) |

Revised: 1/2024

Preferred Pharmaceuticals Inc.