

ACETAMINOPHEN- acetaminophen tablet
Aurohealth LLC

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">• 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 for more than 10 days unless directed by a doctor
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 (100 Caplets Bottle)

AUROHEALTH

NDC 58602-773-21

**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

100 Caplets

500 mg each

Top Layer Printing side

NDC 58602-773-21
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

100 Caplets
500 mg each

Lot: LM-4742

NVZ

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 - muscular aches
 - premenstrual and menstrual cramps
- temporarily reduces fever

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

Contains No Aspirin

Distributed by: Aurohealth LLC,
279 Princeton- Hightstown Road,
East Windsor, NJ 08520
Made in India
Code: TS/DRUGS/16/2014

P 1429095 LM-4742

Lot:
EXP:

Position for Vendor logo

Top Layer adhesive side

P 1429095 LM-4742

Drug Facts (continued)

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- 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

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- 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.

Gluing Area

Als : 120 x 45 mm

Base Layer

Gluing Area

P 1429095 LM-4742

Drug Facts (continued)

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

ACETAMINOPHEN

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-773
Route of Administration	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: O8232NY3SJ)	
PALMITOSTEARIC ACID (UNII: Q8Y7S3B85M)	

Product Characteristics

Color	white (White to off White)	Score	no score
Shape	CAPSULE (Biconvex)	Size	18mm
Flavor		Imprint Code	N79
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-773-21	100 in 1 BOTTLE; Type 0: Not a Combination Product	10/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	10/18/2021	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	manufacture(58602-773)

