

AUROPHEN EXTRA STRENGTH FOR ADULTS- 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 carton is opened, or printed foil seal under cap is torn or missing.**

Inactive ingredients

colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, pregelatinized starch (starch), propylene glycol, sodium starch glycolate, talc, titanium dioxide.

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 58602-755-21

**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 50602-755-21

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
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Drug Facts

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Acetaminophen USP 500 mg	Pain reliever/ fever reducer

Uses

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 - the common cold
 - headache
 - backache
 - minor pain of arthritis
 - toothache
 - 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

P1428330 LM-4565

* Lot: XXXXXXXXXX
EXP: MM/YYYY
Prefix & Variables of Lot, EXP shall be printed online during packing.

Position for Vendor logo

* Lot: XXXXXXXXXX
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Top Layer adhesive side

P1428330

LM-4565

Drug Facts (continued)

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

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- 3 or more alcoholic drinks every day while using this product

Allergy alert: acetaminophen may cause severe skin reactions.

Symptoms may include:

- skin redness
- 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 area of feeding, ask a health professional before use.

Gluing Area

A/s : 120 x 45 mm

Base Layer

P1428330

LM-4565

Drug Facts (continued)

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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)
- take 2 caplets every 6 hours while adults and children 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

ask a doctor

children under 12 years

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

colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, pregelatinized starch (in cap), propylene glycol, sodium starch glycolate, talc, titanium dioxide.

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

Gluing Area

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

AUROPHEN EXTRA STRENGTH FOR ADULTS

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-755
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE (1600000 WAMW) (UNII: RFW2ET671P)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

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:58602-755-07	1 in 1 CARTON	02/26/2016	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-755-12	1 in 1 CARTON	02/26/2016	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-755-14	1 in 1 CARTON	02/26/2016	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-755-29	150 in 1 BOTTLE; Type 0: Not a Combination Product	02/26/2016	

5	NDC:58602-755-34	200 in 1 BOTTLE; Type 0: Not a Combination Product	02/26/2016	
6	NDC:58602-755-35	225 in 1 BOTTLE; Type 0: Not a Combination Product	02/26/2016	
7	NDC:58602-755-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	02/26/2016	
8	NDC:58602-755-21	1 in 1 CARTON	02/26/2016	
8		100 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:58602-755-36	250 in 1 BOTTLE; Type 0: Not a Combination Product	04/13/2020	
10	NDC:58602-755-41	1000 in 1 BOTTLE; Type 0: Not a Combination Product	08/14/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	02/26/2016	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	manufacture(58602-755)

Revised: 11/2023

Aurohealth LLC