

ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet
Aurohealth LLC

Drug Facts

Active ingredient (in each gelcap)

Acetaminophen USP 500 mg

Purpose

Pain reliever/fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscular aches
 - backache
 - minor pain of arthritis
 - the common cold
 - toothache
 - 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 gelcaps every 6 hours while symptoms last • do not take more than 6 gelcaps 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). Avoid high humidity

- **do not use if printed foil seal under cap is torn or missing**

Inactive ingredients

ammonium hydroxide, black iron oxide, colloidal silicon dioxide, FD&C blue #1, FD&C red #3, FD&C red #40, gelatin, hydroxypropyl cellulose, magnesium stearate, polyethylene glycol, pregelatinized starch (maize), propylene glycol, shellac glaze, sodium starch glycolate, talc and titanium dioxide.

Questions or comments?

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 (400 Gelcaps Container Label)

Healthy Living™

Extra Strength

For Adults

PAIN RELIEF

acetaminophen gelcaps 500 mg

Pain Reliever/Fever Reducer

Rapid Release Gels

†Compare

to the active

ingredients in

Extra Strength

Tylenol® Rapid

Release Gels

**DO NOT USE WITH OTHER MEDICINES
CONTAINING ACETAMINOPHEN**

400 Gelcaps

500 mg each

Drug Facts (continued)

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	■ take 2 gelscaps every 6 hours while symptoms last
	■ do not take more than 6 gelscaps 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). Avoid high humidity.
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Questions or comments? call 1-855-274-4122

This product is not manufactured or distributed by McNeil Consumer Healthcare, owner of the registered trademark Extra Strength Tylenol® Rapid Release Gels.

Contains No Aspirin Do not use if printed foil seal under cap is torn or missing

Distributed by:
AUROHEALTH LLC
 279 Princeton-Hightstown Road
 East Windsor, NJ 08520

MADE IN INDIA

Healthy Living Acetaminophen Gelscaps 500 mg, 400 Count Code: TS/DRUGS/16/2014

Healthy Living™

Extra Strength For Adults

PAIN RELIEF

acetaminophen gelscaps 500 mg

Pain Reliever/Fever Reducer

Rapid Release Gels

Compare to the active ingredient in Extra Strength Tylenol® Rapid Release Gels

400 Gelscaps
500 mg each

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

Important: Read all product information before using.

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 Symptoms may include: ■ skin reddening ■ blisters ■ rash
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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.

P1429854 LM-4848
 NVZ

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

ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-746
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
AMMONIA (UNII: 5138Q19F1X)	
FERROSO FERRIC OXIDE (UNII: XMOM87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2Z H5LOQY)	
FD&C RED NO. 40 (UNII: WZ B9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3S)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	

SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	red (and Blue with Grey Band)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	J;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-746-44	400 in 1 BOTTLE; Type 0: Not a Combination Product	02/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	02/18/2022	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	analysis(58602-746) , manufacture(58602-746)

Revised: 11/2023

Aurohealth LLC