

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

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**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"> <li>• take 2 gelcaps every 6 hours while symptoms last</li> <li>• do not take more than 6 gelcaps 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). Avoid high humidity

- **do not use if carton is open. 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 (100 Gelcaps Container Label)**

**AUROHEALTH**

**NDC 58602-745-21**

**FOR ADULTS**

**EXTRA STRENGTH**

**Acetaminophen Gelcaps 500 mg**

**Pain Reliever, Fever Reducer**

**Rapid Release Gels**

**100 GELCAPS**

**500 mg each**

NDC 58602-745-21

FOR ADULTS  
EXTRA STRENGTH

Acetaminophen Gelcaps 500 mg

PainReliever, Fever Reducer

Rapid Release Gels

100 GELCAPS  
500 mg each

**Important:** Read all product information before using.  
**DO NOT USE IF PRINTED FOIL SEAL UNDER CAP IS TORN OR MISSING**  
**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**

**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 ■ 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 #40, FD&C red #40, gelatin, hydroxypropyl cellulose, magnesium stearate, polyethylene glycol, pregelatinized starch (maize), polyethylene glycol, shellac glaze, sodium starch glycolate, talc and titanium dioxide.

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

**Contains No Aspirin**

Distributed by  
AUROHEALTH LLC  
279 Princeton Highway  
East, East Windsor, NJ 08820  
Made in India

Code: T5A0RUS62162014

Lot:  
EXP:

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg (100 Gelcaps Container Carton)**

**AUROHEALTH**

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

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

**NDC 58602-745-21**

**FOR ADULTS**

**EXTRA STRENGTH**

**Acetaminophen**

**Gelcaps 500 mg**

**Pain Reliever, Fever Reducer**

**Rapid Release Gels**

**Actual Size**

**100 GELCAPS**

**500 mg each**



## ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-745
<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
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>FERROSO FERRIC OXIDE</b> (UNII: XM0M87F357)	
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>FD&amp;C BLUE NO. 1</b> (UNII: H3R47K3TBD)	
<b>FD&amp;C RED NO. 3</b> (UNII: PN2ZH5LOQY)	
<b>FD&amp;C RED NO. 40</b> (UNII: WZB9127XOA)	
<b>GELATIN, UNSPECIFIED</b> (UNII: 2G86QN327L)	
<b>HYDROXYPROPYL CELLULOSE, UNSPECIFIED</b> (UNII: 9XZ8H6N6OH)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>SODIUM STARCH GLYCOLATE TYPE A POTATO</b> (UNII: 5856J3G2A2)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	

### Product Characteristics

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

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-745-07	1 in 1 CARTON	01/07/2021	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-745-14	1 in 1 CARTON	01/07/2021	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-745-21	1 in 1 CARTON	01/07/2021	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-745-35	1 in 1 CARTON	01/07/2021	
4		225 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	01/07/2021	

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**Labeler** - Aurohealth LLC (078728447)

**Establishment**

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	analysis(58602-745) , manufacture(58602-745)

Revised: 11/2023

Aurohealth LLC