

**ACETAMINOPHEN - acetaminophen tablet, extended release**  
**Aurohealth LLC**

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***Drug Facts***

***Active ingredient (in each extended-release tablet)***

Acetaminophen USP 650 mg

***Purpose***

Pain reliever/fever reducer

***Uses***

- temporarily relieves minor aches and pains due to:
  - muscular aches
  - backache
  - minor pain of arthritis
  - toothache
  - premenstrual and menstrual cramp
  - headache
  - the common cold
- temporarily reduces fever

***Warnings***

**Liver warning:** This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 tablets in 24 hours, which is the maximum daily amount
- 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 tablets every 8 hours with water</li> <li>• swallow whole; do not crush, chew, split or dissolve</li> <li>• do not take more than 6 tablets in 24 hours</li> <li>• do not use for more than 10 days unless directed by a doctor.</li> </ul>
children under 12 years	<ul style="list-style-type: none"> <li>• do not use</li> </ul>

**Other information**

- store at 20° to 25°C (68° to 77°F). Avoid excessive heat 40°C (104°F).
- **do not use if carton is opened or foil inner seal is broken**
- Meets USP dissolution test 3

**Inactive ingredients**

colloidal silicon dioxide, hydroxyethyl cellulose, hypromellose, magnesium stearate,

microcrystalline cellulose, povidone, pregelatinized starch (maize), sodium starch glycolate, titanium dioxide, triacetin

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/22/2009

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 650 mg (250 Tablet Bottle)**

**AUROHEALTH**

**TO OPEN: 1. PUSH DOWN                      NDC 58602-873-36**  
**2. TURN CAP**

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

**8 HOUR MUSCLE ACHES & PAIN**

**Acetaminophen  
Extended-Release  
Tablets USP  
650 mg**

**Pain Reliever/Fever Reducer  
For up to 8 Hours Relief of  
Minor Muscle Aches & Pain  
250 Extended-release tablets**

<p>MINOR ACHES</p> <p>TO OPEN: 1. PUSH DOWN                      NDC 58602-873-36 2. TURN CAP</p> <p><b>DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN</b></p> <p><b>8 HOUR MUSCLE ACHES &amp; PAIN</b></p> <p><b>Acetaminophen Extended-Release Tablets USP 650 mg</b></p> <p><b>Pain Reliever/Fever Reducer For Up to 8 Hours Relief of Minor Muscle Aches &amp; Pain 250 Extended-release tablets</b></p>		<p>Contains No Aspirin</p> <p>Do not use if foil liner seal is broken.</p> <p><b>Drug Facts</b></p> <p><b>Active ingredient (in each extended-release tablet):</b> <b>Pain reliever/fever reducer</b> Acetaminophen USP 650 mg</p> <p><b>Use:</b> Temporarily relieves minor aches and pains due to: ■ muscle aches ■ backache ■ minor pain of arthritis ■ headache ■ premenstrual and menstrual cramps ■ headache ■ sinus pain ■ temporarily reduces fever</p> <p><b>Warnings</b></p> <p><b>Liver warning:</b> This product contains acetaminophen. Severe liver damage may occur if you take ■ more than 6 tablets in 24 hours, which is the maximum daily amount ■ with other drugs containing acetaminophen ■ 3 or more alcoholic drinks every day while using this product.</p> <p><b>Allergy alert:</b> 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.</p> <p><b>Do not use</b> ■ 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.</p> <p><b>Ask a doctor before use if you have liver disease.</b></p> <p><b>Ask a doctor or pharmacist before use if you are taking the blood thinning drug warfarin.</b></p> <p><b>Stop use and ask a doctor if</b> ■ 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.</p> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children. Overdose warning:</b> 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.</p> <p><b>Directions</b></p> <p>■ <b>do not take more than directed (see overdose warning). Adults and children 12 years and over:</b> ■ take 2 tablets every 8 hours with water ■ swallow whole. Do not crush, chew, split or dissolve ■ do not take more than 6 tablets in 24 hours ■ do not use for more than 10 days unless directed by a doctor. <b>Children under 12 years:</b> ■ do not use</p> <p><b>Other information</b></p> <p>■ store at 20° to 25°C (68° to 77°F). Avoid excessive heat 40°C (104°F). ■ Meets USP dissolution test 3</p> <p><b>Inactive ingredients</b> colloidal silicon dioxide, hydroxyethyl cellulose, hypromellose, polyethylene glycol 400, croscarmellose sodium, polyethylene glycol 6000, pregelatinized starch (maize), sodium starch glycolate, titanium dioxide, triacetin</p> <p><b>Questions or comments?</b> call 1-855-274-4122</p>
<p>P1431313</p> <p>Distributed by: AUROHEALTH LLC 279 Princeton-Hightstown Road East Windsor, NJ 08520 Made in India Code: TS/DRUGS/22/2009</p> <p>IMZ</p>		

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

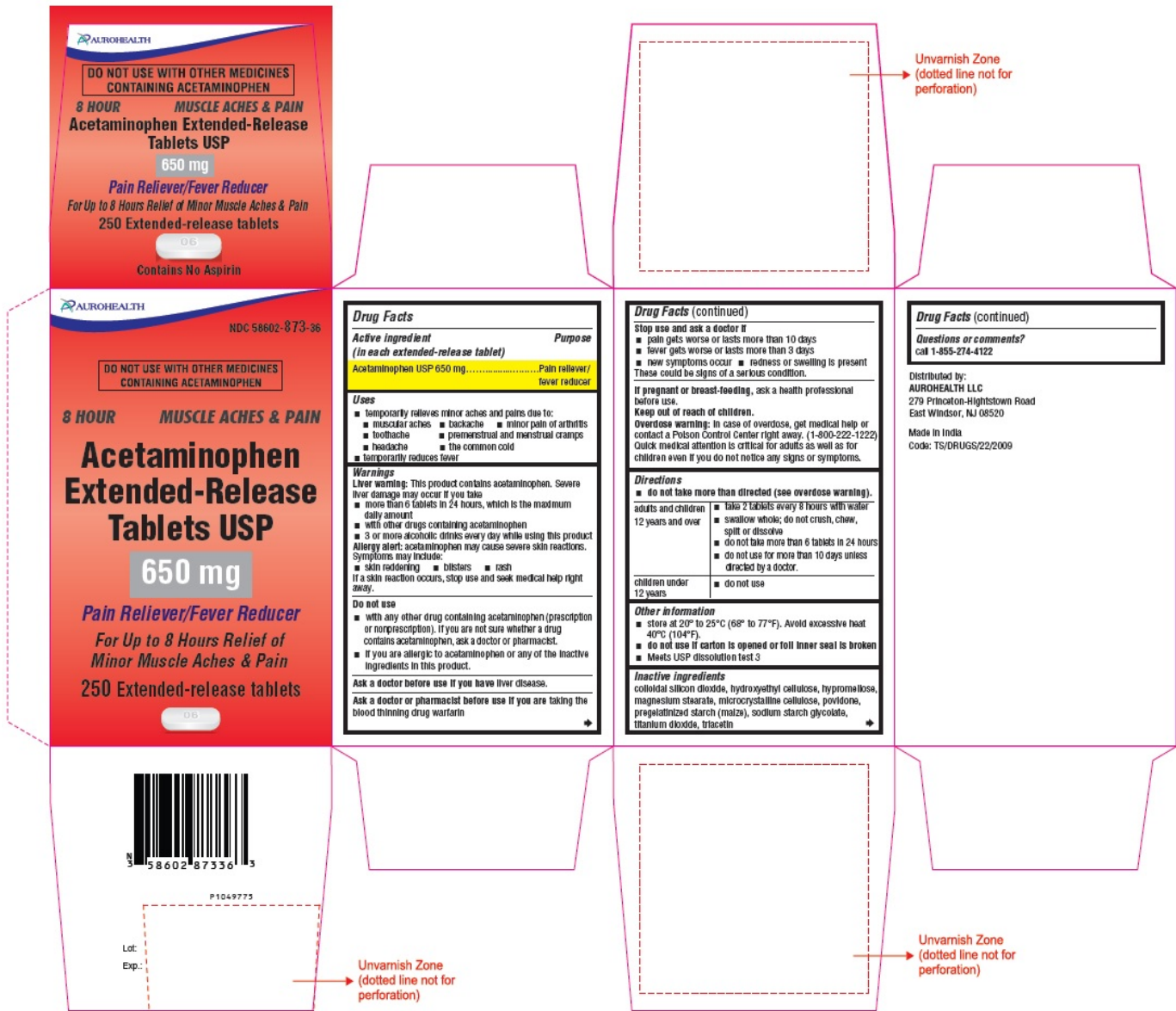
**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 650 mg (250 Tablets Container Carton)**

**AUROHEALTH  
NDC 58602-873-36**

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

***8 HOUR                    MUSCLE ACHES & PAIN***

**Acetaminophen  
Extended-Release  
Tablets USP  
650 mg  
*Pain Reliever/Fever Reducer  
For Up to 8 Hours Relief of  
Minor Muscle Aches & Pain*  
250 Extended-release tablets**



# ACETAMINOPHEN

acetaminophen tablet, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-873
<b>Route of Administration</b>	ORAL		

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>SILICON DIOXIDE</b> (UNII: ETJ7Z6XBU4)	
<b>HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%)</b> (UNII: 8136Y38GY5)	
<b>HYPROMELLOSE, UNSPECIFIED</b> (UNII: 3NXW29V3WO)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>MICROCRYSTALLINE CELLULOSE</b> (UNII: OP1R32D61U)	
<b>POVIDONE, UNSPECIFIED</b> (UNII: FZ989GH94E)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>SODIUM STARCH GLYCOLATE TYPE B POTATO</b> (UNII: 27NA468985)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TRIACETIN</b> (UNII: XHX3C3X673)	

## Product Characteristics

<b>Color</b>	WHITE (White to Off-White)	<b>Score</b>	no score
<b>Shape</b>	CAPSULE (Caplet)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	I;06
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-873-36	1 in 1 CARTON	12/27/2021	
1		250 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-873-07	1 in 1 CARTON	12/27/2021	
2		24 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-873-14	1 in 1 CARTON	12/27/2021	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-873-21	1 in 1 CARTON	12/27/2021	
4		100 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-873-29	1 in 1 CARTON	12/27/2021	
5		150 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-873-34	200 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2021	
7	NDC:58602-873-35	225 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2021	
8	NDC:58602-873-67	290 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2021	
9	NDC:58602-873-76	325 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2021	
10	NDC:58602-873-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2021	

<b>11</b>	NDC:58602-873-41	1000 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2021	
<b>12</b>	NDC:58602-873-94	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2021	
<b>13</b>	NDC:58602-873-44	400 in 1 BOTTLE; Type 0: Not a Combination Product	12/27/2021	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207229	12/27/2021	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-873) , MANUFACTURE(58602-873)

Revised: 1/2024

Aurohealth LLC