

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

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**Drug Facts**

**Active ingredient (in each tablet)**

Acetaminophen USP 325 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. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if

- adult takes more than 4,000 mg of acetaminophen in 24 hours
- child takes more than 5 doses in 24 hours, which is the maximum daily amount
- taken with other drugs containing acetaminophen
- adult has 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 the user has**

liver disease

**Ask a doctor or pharmacist before use if the user is**

taking the blood thinning drug warfarin

**Stop use and ask a doctor if**

- pain gets worse or lasts more than 10 days in adults
- pain gets worse or lasts more than 5 days in children under 12 years
- 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 4 to 6 hours while symptoms last</li><li>• do not take more than 10 tablets 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 6 years to under 12 years	<ul style="list-style-type: none"><li>• take 1 tablet every 4 to 6 hours while symptoms last</li></ul>

	<ul style="list-style-type: none"><li>• do not take more than 5 tablets in 24 hours</li><li>• do not use for more than 5 days unless directed by a doctor</li></ul>
children under 6 years	ask a doctor

### **Other information**

- store between 20° to 25°C (68° to 77°F)
- **do not use if carton is open or if printed foil seal under cap is torn or missing.**

### **Inactive ingredients**

povidone, pregelatinized starch (maize), stearic acid.

### **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 325 mg (100 Tablets Bottle)**

**AUROHEALTH  
NDC 58602-775-21**

**REGULAR STRENGTH  
Pain Relief  
Acetaminophen  
Tablets 325 mg**

**Pain Reliever/  
Fever Reducer**

**100  
Tablets  
325 mg each**

**AUROHEALTH**  
 NDC 58602-775-21  
**REGULAR STRENGTH**  
**Pain Relief**  
**Acetaminophen**  
 Tablets 325 mg  
 Pain Reliever/  
 Fever Reducer  
**100**  
**Tablets**  
 325 mg each

**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**  
 Do not use if printed foil seal under bottle cap is open or torn.

**Purpose**  
 Acetaminophen USP 325 mg.....Pain reliever/fever reducer

**Active ingredient (in each tablet)**  
 ■ temporarily relieves minor aches and pains due to: ■ headache  
 ■ muscular aches ■ backache ■ minor pain of arthritis  
 ■ the common cold ■ headache ■ premenstrual and menstrual cramps  
 ■ temporarily reduces fever

**Warnings**  
 Liver warning: This product contains acetaminophen. The maximum daily dose of this product is 10 tablets (3,250 mg) in 24 hours for adults or 5 tablets (1,625 mg) in 24 hours for children. Severe liver damage may occur if ■ adult takes more than 4,000 mg of acetaminophen in 24 hours ■ child takes more than 5 doses in 24 hours, which is the maximum daily amount ■ taken with other drugs containing acetaminophen ■ adult has 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 the user has liver disease. Ask a doctor or pharmacist before use if the user is taking the blood thinning drug warfarin. Stop use and ask a doctor if ■ pain gets worse or lasts more than 10 days in adults ■ pain gets worse or lasts more than 5 days in children under 12 years ■ 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: (1-800-222-4222) 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 tablets every 4 to 6 hours while symptoms last ■ do not take more than 10 tablets in 24 hours, unless directed by a doctor ■ do not use for more than 10 days unless directed by a doctor, children 6 years to under 12 years ■ take 1 tablet every 4 to 6 hours while symptoms last ■ do not take more than 5 tablets in 24 hours ■ do not use for more than 15 days unless directed by a doctor

**Other information** ■ store between 20° between 25°C (68° to 77°F) ■ do not use if printed foil seal under bottle cap is open or torn

**Inactive ingredients:** polydioxane, pregelatinized starch (maize), stearic acid

**Questions or comments?** call 1-866-274-4122

Distributed by: AUROHEALTH LLC  
 279Pittsford-Highstown Road, East Windsor, NJ 08520  
 Made in India

Code: TSCRLGSI192014  
 P 1429998

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

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 325 mg (100 Tablets Bottle Carton)**

**AUROHEALTH**  
**NDC 58602-775-21**  
**Compare to the active ingredient in**  
**Tylenol® Regular Strength tablets \***

**RREGULAR STRENGTH**  
**Acetaminophen**  
**Tablets 325 mg**

**Pain Reliever/Fever Reducer**

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

Actual size

**100**  
**Tablets**  
**325 mg each**



## ACETAMINOPHEN REGULAR STRENGTH

acetaminophen tablet

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:58602-775
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>ACETAMINOPHEN</b> (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	325 mg

## Inactive Ingredients

Ingredient Name	Strength
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>PALMITOSTEARIC ACID</b> (UNII: Q8Y7S3B85M)	

## Product Characteristics

<b>Color</b>	white (White to off White)	<b>Score</b>	no score
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	N74
<b>Contains</b>			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-775-21	1 in 1 CARTON	02/02/2022	
1		100 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	02/02/2022	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	analysis(58602-775) , manufacture(58602-775)

Revised: 11/2023

Aurohealth LLC