

**AMAZON BASIC CARE ACETAMINOPHEN - acetaminophen tablet, extended release**

**Amazon.com Services 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 cramps
  - 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**

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Made in India

**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 650 mg (24 Tablets Bottle)**

**amazon  
basic+care**

**8 Hour                    NDC 72288-698-10  
Pain Relief**

- 1. push down**
- 2. Turn cap**

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

**Pain Reliever/Fever Reducer  
For up to 8 Hours Relief of  
Minor Muscle Aches and Pain**

**100 CAPLETS\***

**\*CAPSULE-SHAPED TABLETS**

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



**PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 650 mg (24 Tablets Container Carton)**

amazon  
basic+care

**8 Hour Muscle Aches & Pain**                      **NDC 72288-698-10**

**Compare to Tylenol® 8HR Caplets active ingredient\*\***

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

**Pain Reliever/Fever Reducer For up to 8 Hours Relief of Minor Muscle Aches and Pain**

**100 CAPLETS\***

**\*CAPSULE-SHAPED TABLETS**

\*  
Unvarnished Zone  
(dotted line not for printing)  
44 x 12 mm

GLUE - NO COATING

**Drug Facts (continued)**

**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).
- Take 2 tablets every 8 hours with water
- swallow whole; do not crush, chew, spit 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.

children under 12 years

**Other information**

- store at 20° to 25°C (68° to 77°F). Avoid excessive heat, 40°C (104°F).
- do not use if capton is opened or foil liner 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**

\*\*This product is not manufactured or distributed by Johnson and Johnson Consumer Inc., McNeil Consumer Healthcare Division, distributor of Tylenol 8HR Caplets.

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**Drug Facts**

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

Acetaminophen USP 650 mg.....Pain reliever/fever reducer

**Uses**

- temporarily relieves minor aches and pains (due to cold, flu, headache, toothache, backache, minor pain of arthritis, menstrual and menstrual cramps)
- headache
- temporarily reduces fever

**Warnings**

**Important:** 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:

- hives
- rash

If a skin reaction occurs, stop use and seek medical help right away.

**Do not use**

- 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
- redness or swelling is present

These could be signs of a serious condition.

8 Hour Muscle Aches & Pain NDC 72288-698-10

**Acetaminophen**  
Extended-Release Tablets USP, 650 mg  
Pain Reliever/Fever Reducer

Contains No Aspirin  
**DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN**



8 Hour Muscle Aches & Pain NDC 72288-698-10

**Acetaminophen**  
Extended-Release Tablets USP, 650 mg  
Pain Reliever/Fever Reducer

For up to 8 Hours Relief of Minor Muscle Aches and Pain  
100 CAPLETS\*  
\*CAPSULE-SHAPED TABLETS



actual size

basic+care  
Compare to Tylenol® 8HR Caplets active ingredient\*\*



1 95515 104907 8

P1054621 LM-5728

Unvarnished Zone (dotted line not for printing) 65 x 25 mm



8 Hour Muscle Aches & Pain NDC 72288-698-10

**Acetaminophen**  
Extended-Release Tablets USP, 650 mg  
Pain Reliever/Fever Reducer

For up to 8 Hours Relief of Minor Muscle Aches and Pain  
100 CAPLETS\*  
\*CAPSULE-SHAPED TABLETS



actual size

basic+care  
Compare to Tylenol® 8HR Caplets active ingredient\*\*

# AMAZON BASIC CARE ACETAMINOPHEN

acetaminophen tablet, extended release

## Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:72288-698
<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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE B POTATO (UNII: 27NA468985)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (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:72288-698-10	1 in 1 CARTON	05/15/2024	
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
ANDA	ANDA207229	05/15/2024	

**Labeler** - Amazon.com Services LLC (128990418)

**Registrant** - Aurohealth LLC (078728447)

## Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(72288-698) , MANUFACTURE(72288-698)

Revised: 5/2024

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