

**ACETAMINOPHEN- acetaminophen tablet, film coated, extended release  
Granules USA, Inc.**

-----  
**8 Hour  
Arthritis Pain  
Acetaminophen Extended-release Tablets USP, 650 mg  
Pain Reliever/Fever Reducer  
For the Temporary Relief of Minor Arthritis Pain**

**Active ingredient**

(in each caplet)  
Acetaminophen USP, 650 mg

**Purpose**

Pain reliever/fever reducer

**Uses**

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

**Liver warning**

This product contains acetaminophen. Severe liver damage may occur if you take

- more than 6 caplets 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**

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

- take 2 caplets every 8 hours with water

- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor under 18 years of age
- ask a doctor

### **Other information**

- store between 20-25°C (68-77°F)
- **do not use if foil inner seal is broken or missing**

### **Inactive ingredients**

hydroxy ethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid.

### **Questions or comments?**

Contact **1-877-770-3183** Mon-Fri 8:00 AM EST to 5:00 PM PST.

### **Principal Display Panel**



Principal Display Panel

NDC 70010-160-01

TO OPEN: PUSH AND TURN CAP  
READ THE LABEL.

**Compare to the active ingredient  
of Tylenol® 8 HR Arthritis Pain\***

**ARTHRTIS PAIN**

# Acetaminophen

**Extended-release tablets USP, 650 mg**

**Pain Reliever/Fever Reducer**  
**For The Temporary Relief Of Minor Arthritis Pain**  
**Contains No Aspirin**

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

**100 Caplets\*\***  
650 mg each  
(\*\*Capsule-Shaped BI-Layer Tablets)

actual size

**Important: Read all product information before using.**  
**Do not use if foil liner seal is broken or missing.**

**Drug Facts**

**Active Ingredient (in each caplet)**  
Acetaminophen USP, 650 mg

**Uses**

- Temporarily relieves minor aches and pains due to:
  - minor pain of arthritis
  - muscle aches
  - backache
  - premenstrual and menstrual cramps
  - the common cold
  - headache
  - toothache
- Temporarily reduces fever

**Warnings**

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

- more than 6 caplets in 24 hours, which is the maximum safe amount
- with other drugs containing acetaminophen
- 3 or more alcoholic drinks every day while using this product

**Warning:** acetaminophen may cause severe skin reactions. Symptoms may include:

- skin redness
- itching
- hives
- skin rash
- skin reaction occurs, stop use and seek medical help right away.

**Do not use**

- with any other drug containing acetaminophen (prescription or over-the-counter). 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.

(CONTINUED ON BACK OF LABEL)

8 13874-02037 7

LOT EXP

3006530444  
7006530329

MADE IN INDIA

7006530444  
7006530329

MADE IN INDIA

7006530444  
7006530329

MADE IN INDIA

**Inside (adhesive side)**

**Drug Facts (continued)**

**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**

- your pain gets worse or lasts more than 10 days
- your fever worsens or lasts more than 3 days
- new symptoms occur
- you notice or swelling is present
- these could be signs of a serious condition.

**Keep out of reach of children.**

**Overdose warning:** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-422-1222). 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 caplets every 8 hours with water
- swallow whole; do not crush, chew, split or dissolve
- do not take more than 6 caplets in 24 hours
- do not use for more than 10 days unless directed by a doctor
- ask a doctor

**Other Information**

- store between 20-25°C (68-77°F)
- do not use if foil liner seal is broken or missing

**Inactive Ingredients**

hydroxyethylcellulose, hypromellose, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyethylene glycol, sodium starch glycolate, water, wax.

**Questions or comments?**

This product is not manufactured or distributed by Mohel Consumer Healthcare, distributor of Tylenol® 8 HR Arthritis Pain.

## ACETAMINOPHEN

acetaminophen tablet, film coated, extended release

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:69848-015
<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
HYDROXYETHYL CELLULOSE (140 CPS AT 5%) (UNII: 8136Y38GY5)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>MAGNESIUM STEARATE</b> (UNII: 70097M6I30)	
<b>POLYETHYLENE GLYCOL 400</b> (UNII: B697894SGQ)	

### Product Characteristics

<b>Color</b>	white (White to off white colored)	<b>Score</b>	no score
<b>Shape</b>	OVAL (Capsule shaped, biconvex intact film coated tablets)	<b>Size</b>	19mm
<b>Flavor</b>		<b>Imprint Code</b>	G;650
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-015-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	12/31/2019	
2	NDC:69848-015-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	11/30/2022	

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA211544	12/31/2019	

**Labeler** - Granules USA, Inc. (137098864)

Revised: 12/2025

Granules USA, Inc.