

**ACETAMINOPHEN- acetaminophen tablet, extended release**  
**The Kroger Company**

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**Acetaminophen**

***Drug Facts***

**Active ingredient (in each caplet)**

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 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.**

**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 caplets every 8 hours with water</li><li>▪ swallow whole; do not crush, chew, split or dissolve</li><li>▪ do not take more than 6 caplets 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 - 25° C (68 - 77° F). Avoid excessive heat 40° C (104° F).
- see end panel for batch number and expiration date
- **TAMPER EVIDENT: DO NOT USE IF IMPRINTED SEAL IS BROKEN OR MISSING FROM BOTTLE.**

## **Inactive ingredients**

crospovidone, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, propylene glycol, sodium lauryl sulfate, stearic acid, titanium dioxide

## **Questions?**

call **1-800-632-6900**

DISTRIBUTED BY THE KROGER CO.  
CINCINNATI, OHIO 45202

## **PRINCIPAL DISPLAY PANEL - 650 mg Caplet Bottle Carton**

COMPARE TO the active ingredient of  
TYLENOL® 8HR \*See side panel

NDC 30142-968-01

Kroger®

USE ONLY AS DIRECTED

OUR PHARMACIST RECOMMENDED

8 Hour Pain Relief†

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

†For up to 8 Hour Relief of Minor Muscle Aches & Pain

actual  
size

100 CAPLETS\*\*

\*\*capsule-shaped tablets

DO NOT USE WITH OTHER MEDICINES  
CONTAINING ACETAMINOPHEN



## Active Ingredient/Active Moiety

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

## Inactive Ingredients

Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6130)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM LAURYL SULFATE (UNII: 368GB5141J)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
CROSPVIDONE (UNII: 2S7830E561)	

## Product Characteristics

Color	white	Score	no score
Shape	OVAL (Capsule Shaped)	Size	19mm
Flavor		Imprint Code	cor116
Contains			

## Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-968-01	1 in 1 CARTON	02/19/2021	
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	ANDA076200	02/19/2021	

**Labeler** - The Kroger Company (006999528)

**Registrant** - Ohm Laboratories Inc. (051565745)

**Establishment**

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
Ohm Laboratories Inc.		184769029	MANUFACTURE(30142-968)

Revised: 6/2022

The Kroger Company