ACETAMINOPHEN- acetaminophen tablet, extended release The Kroger Company

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	 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
children under 12 years	• do not use

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 †

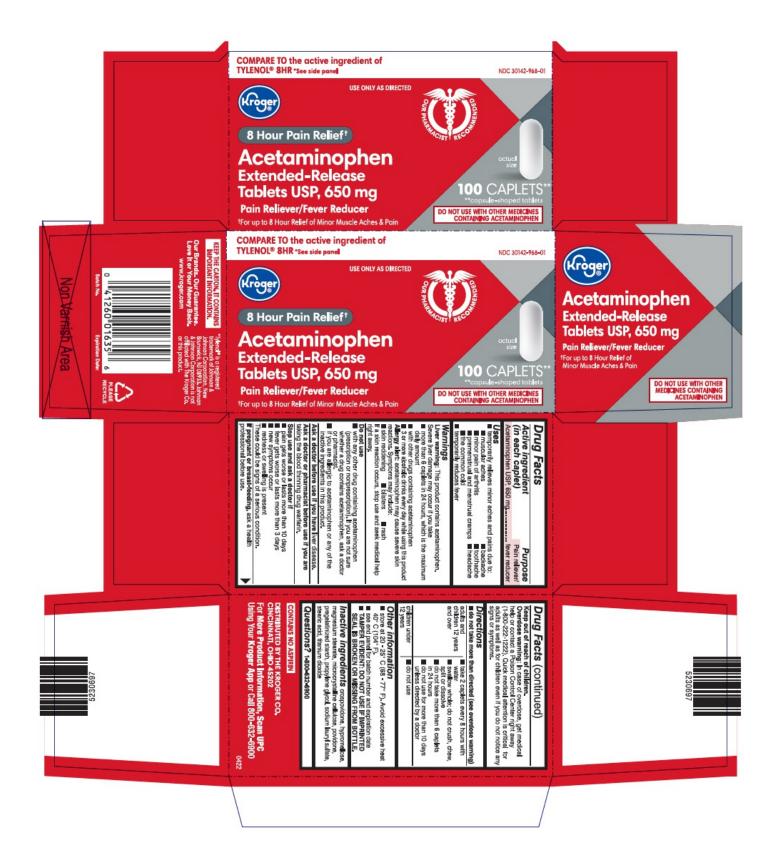
Acetaminophen Extended-Release Tablets USP, 650 mg Pain Reliever/Fever Reducer

[†]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



ACETAMINOPHEN

acetaminophen tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-968
Route of Administration	ORAL		

Active Ingredient/Active Moiety Ingredient Name Basis of Strength ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN (ONII: 36209ITL9D) (ACETAMINOPHEN - UNII: 36209ITL9D)

Inactive Ingredients	
Ingredient Name	Strength
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
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)	
CROSPOVIDONE (UNII: 2S7830E561)	

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

Packaging				
# Item Co	ode	Package Description	Marketing Start Date	Marketing End Date
1 NDC:30142	2-968- 1 in	n 1 CARTON	02/19/2021	12/31/2025
1		0 in 1 BOTTLE; Type 0: Not a Combination oduct		

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA076200	02/19/2021	12/31/2025

Labeler - The Kroger Company (006999528)

Registrant - Ohm Laboratories Inc. (051565745)

Establishment

Name	Address	ID/FEI	Business Operations
Ohm Laboratories Inc.		184769029	manufacture(30142-968)

Revised: 1/2025 The Kroger Company