ACETAMINOPHEN EXTRA STRENGTH - acetaminophen tablet
KROGER COMPANY

Drug Facts

Active ingredient (in each gelcap)

Acetaminophen USP 500 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. Severe liver damage may occur if you take

- more than 4,000 mg of acetaminophen in 24 hours
- 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 (1-800-222-1222) right away.

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 gelcaps every 6 hours while symptoms last • do not take more than 6 gelcaps in 24 hours, unless directed by a doctor • do not use for more than 10 days unless directed by a doctor
children under 12 years	ask a doctor

Other information

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

Inactive ingredients

ammonium hydroxide, black iron oxide, colloidal silicon dioxide, FD&C blue #1, FD&C red #3, FD&C red #40, gelatin, hydroxypropyl cellulose, magnesium stearate, polyethylene glycol, pregelatinized starch (maize), propylene glycol, shellac glaze, sodium starch glycolate, talc and titanium dioxide.

Questions or comments?

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

DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202
MADE IN INDIA

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg (24 Gelcaps Container Label)

NDC 30142-068-07

Kroger®
health

FOR ADULTS
EXTRA STRENGTH
Acetaminophen
500 mg

PAIN RELIEVER/
FEVER REDUCER

24 RAPID RELEASE
GELCAPS
500 mg EACH

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg (24 Gelcaps Container Carton Label)

NDC 30142-068-07

Kroger®
health

COMPARE TO THE ACTIVE INGREDIENT IN
EXTRA STRENGTH TYLENOL® RAPID RELEASE GELS*

EXTRA STRENGTH FOR ADULTS
Acetaminophen 500 mg

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

PAIN RELIEVER/
FEVER REDUCER

24 RAPID RELEASE
GELCAPS 500 mg EACH ACTUAL SIZE

ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:30142-068
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	500 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
FD&C RED NO. 3 (UNII: PN2ZH5LOQY)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYDROXYPROPYL CELLULOSE, UNSPECIFIED (UNII: 9XZ8H6N6OH)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B71O)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	RED (and Blue with Grey Band)	**Score**	no score
Shape	CAPSULE	**Size**	19mm
Flavor		**Imprint Code**	J;1
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-068-07	1 in 1 CARTON	02/04/2021	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:30142-068-35	1 in 1 CARTON	04/26/2021	
2		225 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:30142-068-24	1 in 1 CARTON	04/22/2024	
3		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	02/04/2021	

Labeler - KROGER COMPANY (006999528)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(30142-068) , MANUFACTURE(30142-068)

Revised: 10/2024 KROGER COMPANY