# ACETAMINOPHEN EXTRA STRENGTH - acetaminophen tablet KROGER COMPANY

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# **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 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> <li>take 2 gelcaps every 6 hours while symptoms last</li> <li>do not take more than 6 gelcaps in 24 hours, unless directed by a doctor</li> <li>do not use for more than 10 days unless directed by a doctor</li> </ul>
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?

1-800-632-6900

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

**Distributed by:** THE KROGER CO. CINCINNATI, OHIO 45202 Made in India

Code: TS/DRUGS/16/2014

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

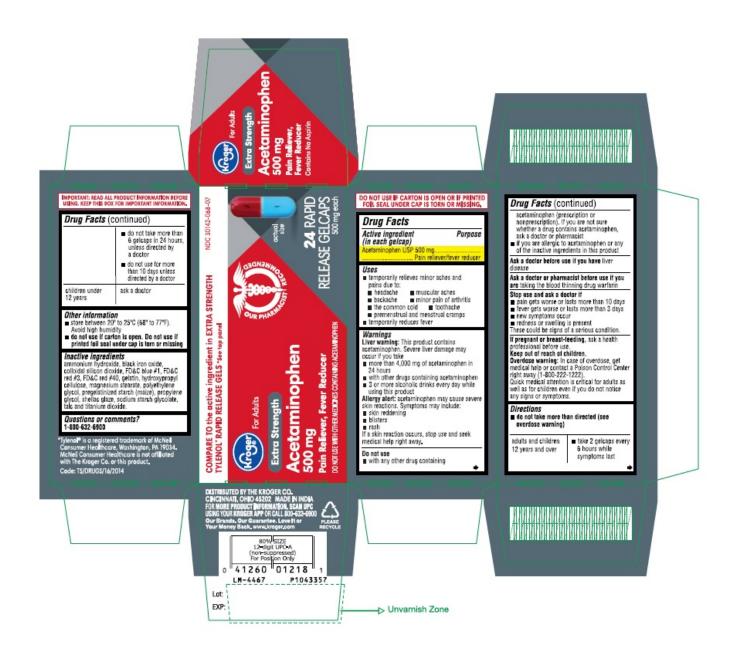
NDC 30142-068-07
Kroger® For Adults
Extra Strength
Acetaminophen
500 mg
Pain Reliever,
Fever Reducer
24
RAPID
RELEASE
GELCAPS
500 mg each



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

COMPARE TO the active ingredient in EXTRA STRENGTH TYLENOL® RAPID RELEASE GELS \*See top panel NDC 30142-068-07

Kroger® For Adults
Extra Strength
Acetaminophen
500 mg
Pain Reliever, Fever Reducer
DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN
actual
size
24 RAPID
RELEASE GELCAPS
500 mg each



### 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 ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D) ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)

# **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: 3WJQ0SDW1A)	
STARCH, CORN (UNII: 08232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SHELLAC (UNII: 46N107B710)	
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	

# Registrant - Aurohealth LLC (078728447)

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

Revised: 4/2024 KROGER COMPANY