# ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet KROGER COMPANY

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#### **Drug Facts**

## Active ingredient (in each caplet)

Acetaminophen USP 500 mg

#### **Purpose**

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
  - the common cold
  - headache
  - backache
  - minor pain of arthritis
  - toothache
  - muscular aches
  - 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 caplets every 6 hours while symptoms last</li> <li>do not take more than 6 caplets 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)
- do not use is carton is open or printed foil seal under cap is torn or missing.

## **Inactive ingredients**

povidone, pregelatinized starch (maize), stearic acid.

#### Questions or comments?

1-800-632-6900

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

Code: TS/DRUGS/16/2014

## PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg (24 Caplets Bottle)

NDC 30142-033-07
Kroger ®
for adults
Extra Strength
Acetaminophen
Caplets 500 mg
Pain Reliever/
Fever Reducer
SEE NEW WARNINGS
INFORMATION &
DIRECTIONS

**24** CAPLETS

500 mg EACH



★ Lot: XXXXXXXXX EXP: MM/YYYY Prefix & Variables of Lot, EXP shall be printed online during packing.

# PACKAGE LABEL-PRINCIPAL DISPLAY PANEL 500 mg (24 Caplets Bottle Carton)

**COMPARE TO the active ingredient of** 033-07

NDC 30142-

EXTRA STRENGTH TYLENOL <sup>®</sup>CAPLETS \*See top panel Kroger <sup>®</sup>

for adults SEE NEW WARNINGS INFORMATION & DIRECTIONS

Extra Strength
Acetaminophen Caplets
500 mg
Pain Reliever/Fever Reducer
DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

actual size

**24** CAPLLETS 500 mg EACH



#### **ACETAMINOPHEN EXTRA STRENGTH**

acetaminophen tablet

<b>Product Information</b>				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-033	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
	edient Name	Basis o	of Strength Strength	

500 mg

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

Inactive Ingredients		
Ingredient Name	Strength	
POVIDONE K30 (UNII: U725QWY32X)		
STARCH, CORN (UNII: 08232NY3SJ)		
PALMITOSTEARIC ACID (UNII: Q8Y7S3B85M)		

Product Characteristics			
Color	white (White to off White)	Score	no score
Shape	CAPSULE (Biconvex)	Size	18mm
Flavor		Imprint Code	N79
Contains			

F	Packaging				
#	# Item Code Package Description		Marketing Start Date	Marketing End Date	
1	NDC:30142-033- 07	1 in 1 CARTON	02/02/2022		
1		24 in 1 BOTTLE; Type 0: Not a Combination Product			

Marketing Information			
Marketing Application Number or Monograph Category Citation		Marketing Start Date	Marketing End Date
OTC Monograph Drug	M013	02/02/2022	

# Labeler - KROGER COMPANY (006999528)

# Registrant - Aurohealth LLC (078728447)

Establishment				
Name	Address	ID/FEI	Business Operations	
APL HEALTHCARE LIMITED		650844777	analysis(30142-033), manufacture(30142-033)	

Revised: 12/2023 KROGER COMPANY