

ACETAMINOPHEN EXTRA STRENGTH- acetaminophen tablet
KROGER COMPANY

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 style="list-style-type: none">• take 2 caplets every 6 hours while symptoms last• do not take more than 6 caplets 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)
- **do not use if carton is open or printed foil seal under cap is torn or missing.**

Inactive ingredients

colloidal silicon dioxide, hydroxypropyl cellulose, hypromellose, magnesium stearate, polyethylene glycol, pregelatinized starch (maize), propylene glycol, sodium starch glycolate, talc, titanium dioxide.

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 30142-165-07

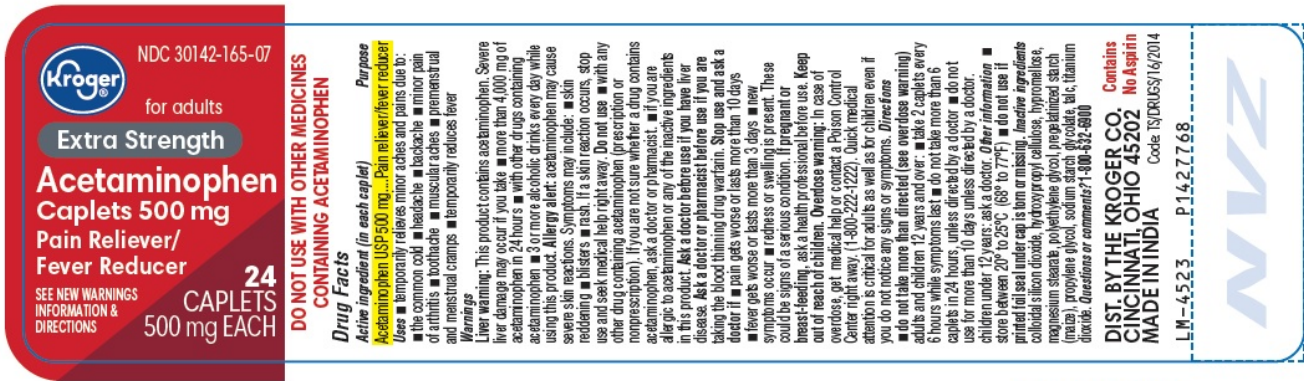
Kroger®

for adults

**Extra Strength
Acetaminophen
Caplets 500 mg
Pain Reliever/
Fever Reducer**

SEE NEW WARNINGS
INFORMATION &
DIRECTIONS

24
CAPLETS
500 mg EACH



* Lot: XXXXXXXX
 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 165-07

NDC 30142-

EXTRA STRENGTH TYLENOL[®] CAPLETS * See top panel Kroger[®]

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 CAPPLETS
 500 mg EACH**



ACETAMINOPHEN EXTRA STRENGTH

acetaminophen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:30142-165
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
HYDROXYPROPYL CELLULOSE (110000 WAMW) (UNII: 5Y0974F5PW)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
STARCH, CORN (UNII: O8232NY3SJ)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

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

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:30142-165-07	1 in 1 CARTON	03/06/2021	
1		24 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	03/06/2021	

Labeler - KROGER COMPANY (006999528)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	analysis(30142-165) , manufacture(30142-165)