# ACETAMINOPHEN- acetaminophen tablet, film coated Kroger Company

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

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# Kroger Co. Acetaminophen Drug Facts

### Active ingredient (in each caplet)

Acetaminophen 500 mg

#### Purpose

Pain reliever/fever reducer

#### Uses

- temporarily relieves minor aches and pains due to:
- the common cold
- minor pain of arthritis
- muscular aches
- headache
- backache
- 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 have ever had an allergic reaction to this product or any of its ingredients

## 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 at 20-25°C (68-77°F)

# **Inactive ingredients**

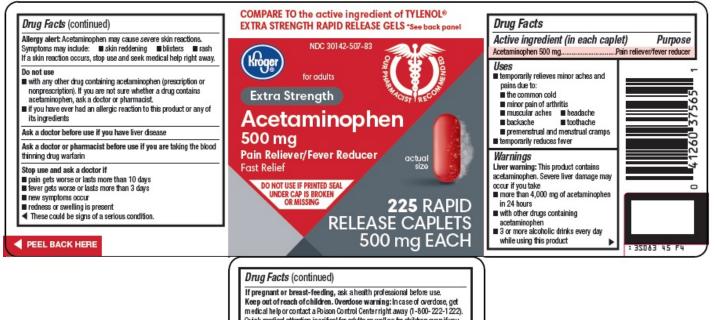
croscarmellose sodium, crospovidone, FD&C red #40 aluminum lake, FD&C yellow #6 aluminum lake, hypromellose, mica-based pearlescent pigment, polyethylene glycol, polysorbate 80, povidone, pregelatinized starch, stearic acid

#### **Questions or comments?**

1-800-632-6900

# Package/Label Principal Display Panel

COMPARE TO the active ingredient of TYLENOL<sup>®</sup> EXTRA STRENGTH RAPID RELEASE GELS See back panel OUR PHARMACIST RECOMMENDED for adults Extra Strength Acetaminophen 500 mg Pain Reliever/Fever Reducer Fast Relief actual size DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING 225 RAPID RELEASE CAPLETS 500 mg EACH



do not notice any s	igns or symptoms.
Directions do not take mo	re than directed (see overdose warning)
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children under 12 years	ask a doctor
Other inform	ation ■ store at 20-25°C (68-77°F)
red #40 aluminum mica-based pearle	e <b>dients</b> croscarmellose sodium, crospovidone, FD&C lake, FD&C yellow #6 aluminum lake, hypromellose, scent pigment, polyethylene glycol, polysorbate 80, irized starch, stearic acid
Questions or	comments? 1-800-632-6900
New Brunswick, N	tered trademark of Johnson & Johnson Corporation, 1J 08933. Johnson & Johnson Corporation is not 9 Kroger Ca. or this product.
DISTRIBUTED THE KROGER CINCINNATI,	CO.
QUALITY GUA 800-632-690 www.kroger.	00
GLUTEN FREE	50m
	ADHESIVE AREA

NO COPY

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ACETAMINOPHEN							
acetaminophen tablet, film c	oated						
Product Information							
Product Type	HUMAN OTC	DRUG	Item Code (Source)			DC:30142-507	
Route of Administration	ORAL						
Active Ingredient/Active	e Moiety						
Ing	redient Nan	ne		Basis of S	trength	Strength	
ACETAMINOPHEN (UNII: 36209)	TL9D) (ACETAMI	NOPHEN - UNI	I:36209ITL9D)	ACETAMINOPH	-	500 mg	
Inactive Ingredients							
	Ingredie	ent Name			S	trength	
CROSCARMELLOSE SODIUM (L	INII: M28OL1HH4	48)					
CROSPOVIDONE (15 MPA.S AT	<b>5%)</b> (UNII: 684	01960MK)					
HYPROMELLOSE, UNSPECIFIEI	<b>)</b> (UNII: 3NXW29	V3WO)					
POLYETHYLENE GLYCOL, UNS	PECIFIED (UNII:	: 3WJQ0SDW1A	A)				
POLYSORBATE 80 (UNII: 60ZP3	9ZG8H)						
POVIDONE, UNSPECIFIED (UNII							
STEARIC ACID (UNII: 4ELV7Z65A	P)						
FD&C RED NO. 40 (UNII: WZ B91	.27XOA)						
FD&C YELLOW NO. 6 (UNII: H7	7VEI93A8)						
Product Characteristics	5						

Color	RED	Score	no score
Shape	OVAL	Size	18mm
Flavor		Imprint Code	350
Contains			

P	Packaging					
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:30142-507- 62	1 in 1 CARTON	08/18/2015	02/28/2023		
1		24 in 1 BOTTLE; Type 0: Not a Combination Product				
2	NDC:30142-507- 78	1 in 1 CARTON	08/18/2015			
2		100 in 1 BOTTLE; Type 0: Not a Combination Product				
3	NDC:30142-507- 83	1 in 1 CARTON	08/21/2015			
3		225 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 not final	part343	08/18/2015			

# Labeler - Kroger Company (006999528)

Revised: 11/2022

Kroger Company