ARTHRITIS PAIN RELIEF- acetaminophen tablet, extended release KROGER COMPANY

Kroger Acetaminophen Extended Release Tablets 650 mg (Arthritis Pain)

Drug Facts

Active ingredient (in each caplet)

Acetaminophen 650 mg

Purpose

Pain reliever/fever reducer

Uses

temporarily relieves minor aches and pains due to:

- minor pain of arthritis
- muscular aches
- backache
- premenstrual and menstrual cramps
- the common cold
- headache
- toothache

temporarily reduces fever

Warnings

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take:

- more than 6 caplets in 24 hours, which is the maximum daily amount
- 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	 take 2 caplets every 8 hours with water swallow whole; do not crush, chew, split, or dissolve do not take more than 6 caplets in 24 hours do not use for more than 10 days unless directed by a doctor
under 18 years of age	ask a doctor

Other information

- store between 20-25°C (68-77°F)
- The FDA approved dissolution methods differ from USP

Inactive ingredients carnauba wax, hydroxyethyl cellulose, hypromellose, magnesium stearate, microcrystalline cellulose, povidone, pregelatinized starch, sodium starch glycolate, titanium dioxide, triacetin

Questions or comments? Call 1-800-632-6900





Arthritis Pain Relief Acetaminophen Extended-Release

Tablets USP, 650 mg LASTS UP TO 8 HOURS FOR THE TEMPORARY RELIEF OF MINOR ARTHRITIS PAIN

DO NOT USE WITH OTHER MEDICINES CONTAINING ACETAMINOPHEN

PAIN RELIEVER/FEVER REDUCER

100 CAPLETS

*CAPSULE-SHAPED BI-LAYER TABLETS

TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Active ingredient (in each caplet)

Orua Facts

Purpose

Uses

■ temporarily relieves minor aches and pains due to:
■ minor pain of arthritis ■ muscular aches ■ backache
■ premenstrual and menstrual cramps ■ the common cold
■ headache ■ toothache
■ temporarily reduces fever

Liver warning: This product contains acetaminophen. Severe liver damage may occur if you take. ■ more than 6 caplets in 24 hours, which is the maximum daily amount ■ 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.

if pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children.

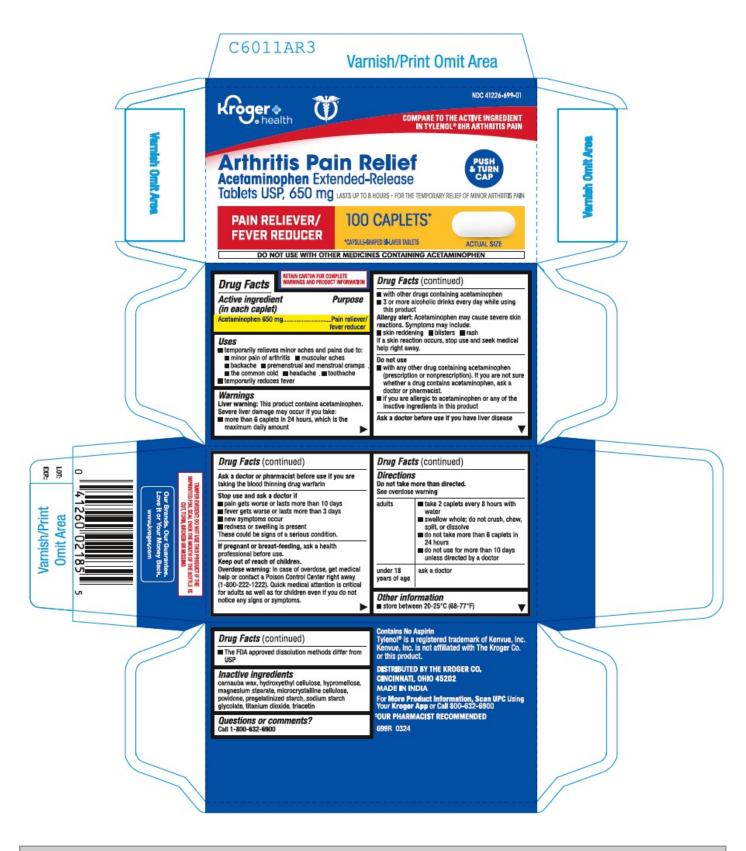
adults: ■ take 2 caplets every 8 hours with water ■ swallow whole; do not crush, chew, split or dissolve ■ do not take more than 6 caplets in 24 hours ■ do not use for more than 10 days unless directed by a doctor Directions Do not take more than directed. See overdose warning under 18 years of age adults: ask a doctor

DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202 Made in India **Questions or comments?** Call 1-800-632-6900

*OUR PHARMACIST RECOMMENDED

- 699R 0324

Varnish Omit Area



ARTHRITIS PAIN RELIEF

acetaminophen tablet, extended release

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-699
Route of Administration	ORAL		

Active Ingredient/Active Moiety

TRIACETIN (UNII: XHX3C3X673)

Ingredient Name		Basis of Strength	Strength
I	ACETAMINOPHEN (UNII: 36209ITL9D) (ACETAMINOPHEN - UNII:36209ITL9D)	ACETAMINOPHEN	650 mg

Inactive Ingredients				
Ingredient Name	Strength			
POVIDONE K30 (UNII: U725QWY32X)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
STARCH, CORN (UNII: O8232NY3SJ)				
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)				
HYDROXYETHYL CELLULOSE (140 MPA.S AT 5%) (UNII: 8136Y38GY5)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)				
CARNAUBA WAX (UNII: R12CBM0EIZ)				
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)				

Product Characteristics			
Color	white (White to off white)	Score	no score
Shape	CAPSULE (Capsule-Shaped Tablet)	Size	19mm
Flavor		Imprint Code	71
Contains			

ı	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
:	NDC:41226-699- 01	1 in 1 CARTON	04/15/2024		
:	L	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
ANDA	ANDA215486	04/15/2024	

Labeler - KROGER COMPANY (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Na me	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-699)

Revised: 4/2024 KROGER COMPANY