

**8 HOUR PAIN RELIEF- acetaminophen tablet, extended release  
KROGER COMPANY**

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**Kroger Acetaminophen Extended-Release Tablets USP 650 mg (Muscle Aches & 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:

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

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

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adults and children 12 years and over	<ul style="list-style-type: none"><li>• take 2 caplets every 8 hours with water</li><li>• swallow whole; do not crush, chew, split, or dissolve</li><li>• do not take more than 6 caplets in 24 hours</li><li>• do not use for more than 10 days unless directed by a doctor</li></ul>
children under 12 years	<ul style="list-style-type: none"><li>• do not use</li></ul>

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**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**



NDC 41226-704-01

8 HOUR PAIN RELIEF

# Acetaminophen Extended-Release Tablets USP, 650 mg

FOR UP TO 8 HOUR RELIEF OF MINOR MUSCLE ACHES & PAIN

**PAIN RELIEVER/  
FEVER REDUCER**

**100 CAPLETS\***

\*CAPSULE-SHAPED BI-LAYER TABLETS

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

**RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION**

**TAMPER EVIDENT: DO NOT USE THIS PRODUCT IF THE IMPRINTED FOIL SEAL OVER THE MOUTH OF THE BOTTLE IS CUT, TORN, BROKEN OR MISSING**

### Drug Facts

#### Active ingredient (in each caplet)

Acetaminophen 650 mg

**Purpose**  
Pain reliever/fever reducer

**Uses** ■ temporarily relieves minor aches and pains due to: muscular aches, backache, minor pain of arthritis, toothache, premenstrual and menstrual cramps, headache, the common cold ■ 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 redness ■ 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. 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: ■ 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

■ children under 12 years: do not use

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

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

Contains No Aspirin

**DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202**

**MADE IN INDIA**

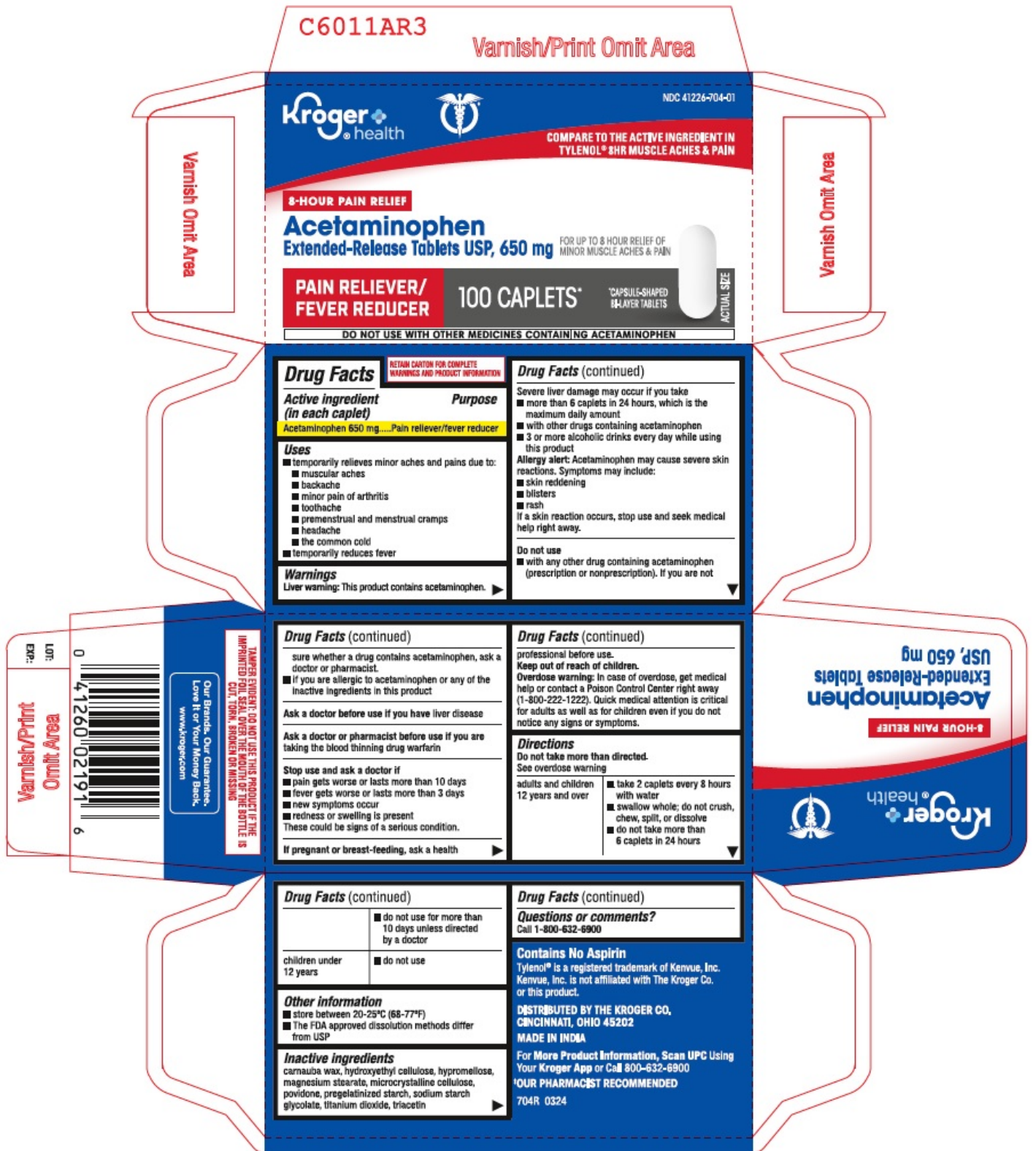
**YOUR PHARMACIST RECOMMENDED**

704R 0324

**LOT:**

**EXP:**

Varnish Omit Area



## 8 HOUR PAIN RELIEF

acetaminophen tablet, extended release

### Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:41226-704

Route of Administration ORAL

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	650 mg

### Inactive Ingredients

Ingredient Name	Strength
POVIDONE K30 (UNII: U725QWY32X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
STARCH, CORN (UNII: O8232NY3SJ)	
SODIUM STARCH GLYCOLATE TYPE A (UNII: H8AV0SQX4D)	
HYDROXYETHYL CELLULOSE (140 MPAS AT 5%) (UNII: 8136Y38GY5)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	

### Product Characteristics

Color	white (White to off white)	Score	no score
Shape	CAPSULE (Capsule-shaped tablet)	Size	19mm
Flavor		Imprint Code	71
Contains			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-704-01	1 in 1 CARTON	04/15/2024	
1		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

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-704)

Revised: 4/2024

KROGER COMPANY