

DUAL ACTION- acetaminophen, ibuprofen tablet
KROGER COMPANY

716R Kroger 41226-716 Acetaminophen and Ibuprofen Tablets 250 mg/ 125 mg

Drug Facts

Active ingredients (in each caplet)

Acetaminophen 250 mg

Ibuprofen 125 mg (NSAID*)

*nonsteroidal anti-inflammatory drug

Purposes

Pain reliever

Pain reliever

Uses

temporarily relieves minor aches and pains due to:

- headache
- toothache
- backache
- menstrual cramps
- muscular aches
- minor pain of arthritis

Warnings

Acetaminophen liver damage warning:

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

- with other drugs containing acetaminophen
- more than 6 caplets in 24 hours, which is the maximum daily amount for this product
- 3 or more alcoholic drinks every day while using this product

Acetaminophen allergy alert: may cause severe skin reactions. Symptoms may include:

- skin reddening
- blisters
- rash

If skin reaction occurs, stop use and seek medical help right away.

NSAID allergy alert: ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- hives
- facial swelling

- asthma (wheezing)
- shock
- skin reddening
- rash
- blisters

If an allergic reaction occurs, stop use and seek medical help right away.

NSAID stomach bleeding warning:

This product contains an NSAID, which may cause severe stomach bleeding. The chance is higher if you:

- are age 60 or older
- have had stomach ulcers or bleeding problems
- take a blood thinning (anticoagulant) or steroid drug
- take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others]
- have 3 or more alcoholic drinks every day while using this product
- take more or for a longer time than directed

Heart attack and stroke warning: NSAIDs, except aspirin, increase the risk of heart attack, heart failure, and stroke. These can be fatal. The risk is higher if you use more than directed or for longer than directed.

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 acetaminophen or any other pain reliever
- right before or after heart surgery

Ask a doctor before use if

- you have liver disease
- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- taking any other drug

When using this product

- take with food or milk if stomach upset occurs

Stop use and ask a doctor if

you experience any of the following signs of stomach bleeding:

- feel faint
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better

you have symptoms of heart problems or stroke:

- chest pain
- trouble breathing
- weakness in one part or side of body
- slurred speech
- leg swelling

pain gets worse or lasts more than 10 days
redness or swelling is present in the painful area

any new symptoms appear

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless definitely directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt 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**

adults and children 12 years and over • **take 2 caplets every 8 hours** while symptoms persist

children under 12 years • ask a doctor

- do not take more than 6 caplets in 24 hours, unless directed by a doctor

Other information

- read all warnings and directions before use. Keep carton.
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients colloidal anhydrous silica, corn starch, croscarmellose sodium, glyceryl dibehenate, hypromellose, microcrystalline cellulose, polydextrose, povidone, red iron oxide, titanium dioxide, triacetin, yellow iron oxide.

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



NDC 41226-716-49

Dual Action

Acetaminophen and Ibuprofen (NSAID) Tablets 250 mg /125 mg

Pain Reliever

Contains 2 Medicines

144 CAPLETS*

*capsule-shaped 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

Do not use with other medicines containing ACETAMINOPHEN; can cause liver damage.

Drug Facts

Active Ingredients (in each caplet)

Acetaminophen 250 mg; Ibuprofen 125 mg (NSAID)*

Nonsteroidal anti-inflammatory drug (NSAID) temporarily relieves minor aches and pains due to: toothache, backache, menstrual cramps, muscular aches, minor pain or arthritis

Warnings

Acetaminophen liver damage 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 for this product. 3 or more alcoholic drinks every day while using this product.

Acetaminophen allergy alert: may cause severe skin reactions. Symptoms may include: skin reddening, blisters, rash. If skin reaction occurs, stop use and seek medical help right away.

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Questions or comments? Call 1-800-632-6900. MADE IN INDIA. DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202

716R 0123

Varnish Omit Area

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COMPARE TO the active ingredients in ADVIL® DUAL ACTION WITH ACETAMINOPHEN †See side panel

NDC 41226-716-49



Dual Action

Acetaminophen and Ibuprofen (NSAID) Tablets 250 mg/125 mg

Pain Reliever



ACTUAL SIZE

144 CAPLETS*

*capsule-shaped tablets

Varnish Omit

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Dual Action

Acetaminophen and Ibuprofen (NSAID) Tablets 250 mg/125 mg

Pain Reliever



ACTUAL SIZE

144 CAPLETS*

*capsule-shaped tablets

Varnish Omit



2

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

Ask a doctor or pharmacist before use if you are under a doctor's care for stroke, because ibuprofen may decrease this benefit of aspirin. Taking any other drug when using this product. Take with food or milk if stomach upset occurs. Stop use and ask a doctor if you experience any of the following signs of stomach bleeding: vomit blood, feel faint, have bloody or black stools, have stomach pain that does not get better.

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Drug Facts (continued) Directions: Do not take more than directed. Adults and children 12 years and over: take 2 caplets every 8 hours while symptoms persist. Children under 12 years: ask a doctor. Do not take more than 6 caplets in 24 hours, unless directed by a doctor. Other information: Read all warnings and directions before use. Keep carton. Store at 20-25°C (68-77°F). Avoid excessive heat above 40°C (104°F).

Drug Facts (continued) If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen at 20 weeks or later in pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222). Prompt medical attention is critical for adults as well as for children even if you do not notice any signs or symptoms.

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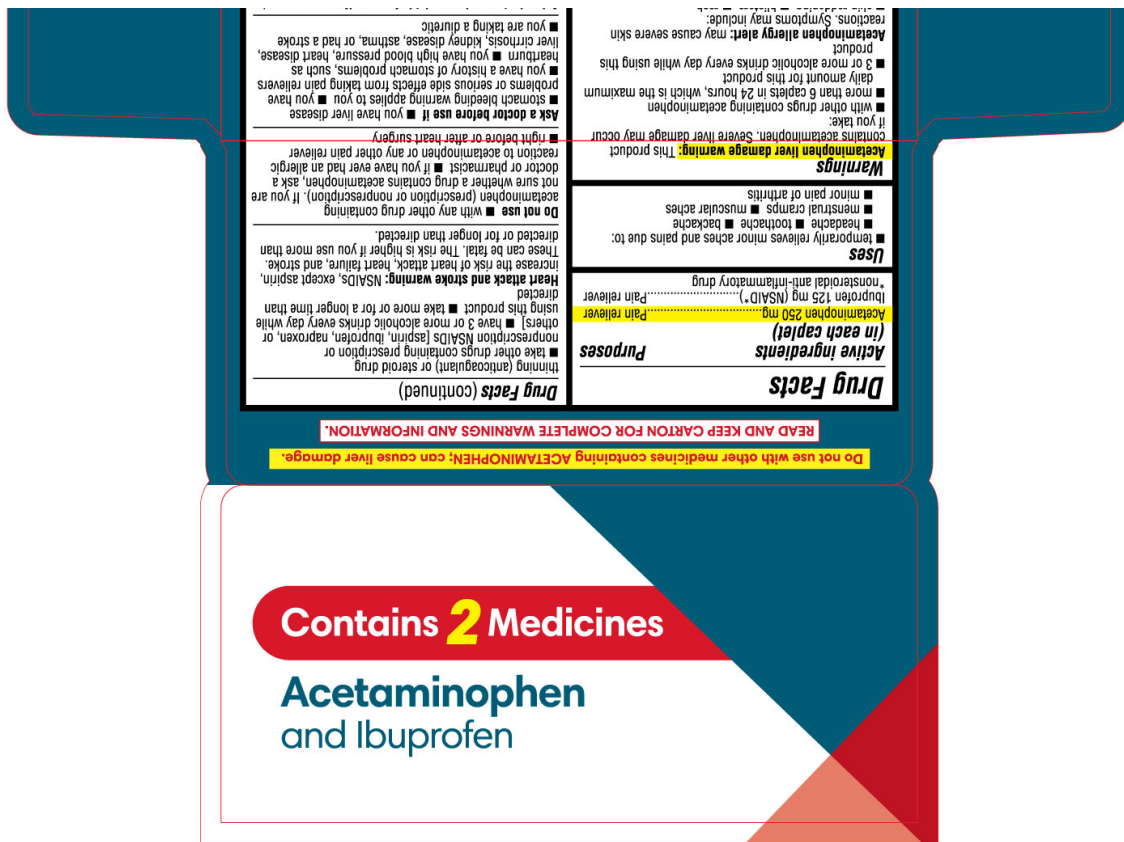
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MADE IN INDIA

For More Product Information, Scan UPC Using Your Kroger App or Call 800-632-6900



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DUAL ACTION

acetaminophen, ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-716
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	250 mg
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	125 mg

Inactive Ingredients

Ingredient Name	Strength
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
GLYCERYL DIBEHENATE (UNII: R8WTH25YS2)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POVIDONE (UNII: FZ989GH94E)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

SILICON DIOXIDE (UNII: ETJ7Z6XBU4)

STARCH, CORN (UNII: O8232NY3SJ)

FERRIC OXIDE RED (UNII: 1K09F3G675)

Product Characteristics

Color	yellow	Score	no score
Shape	CAPSULE (Capsule Shaped Tablets)	Size	15mm
Flavor		Imprint Code	80
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-716-49	1 in 1 CARTON	07/11/2023	
1		144 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	ANDA216994	07/11/2023	

Labeler - KROGER COMPANY (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-716)

Revised: 7/2023

KROGER COMPANY