

**IBUPROFEN- ibuprofen capsule, liquid filled**  
**KROGER COMPANY**

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**Kroger Ibuprofen 200 mg capsules minis**

***Drug Facts***

***Active ingredient (in each capsule)***

Solubilized ibuprofen equal to

200 mg ibuprofen (NSAID)\*

(present as the free acid and potassium salt)

\*nonsteroidal anti-inflammatory drug

***Purpose***

Pain reliever/Fever reducer

***Uses***

temporarily relieves minor aches and pains due to:

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

temporarily reduces fever

***Warnings***

**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.

**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**

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- 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  
fever gets worse or lasts more than 3 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).

***Directions***

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

***Other information***

- **each capsule contains:**potassium 20 mg
- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F).

***Inactive ingredients***ammonium hydroxide, FD&C green no.3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, shellac, sorbitan monooleate, sorbitol sorbitan

***Questions or comments?***

Call **1-800-632-6900**

NDC 41226-700-80

**Kroger** health

**Ibuprofen**

Solubilized Ibuprofen Capsules 200 mg

**MINIS**  
SMALLER SOFTGEL  
SAME STRENGTH

**PAIN RELIEVER/  
FEVER REDUCER  
(NSAID)**

**80 SOFTGELS**

LIQUID-FILLED CAPSULES

**DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING**

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

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

temporarily reduces fever

**Warnings**

**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.

**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.

**If pregnant or breast-feeding,** ask a health professional before use. **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).

**Directions** do not take more than directed the smallest effective dose should be used adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist if pain or fever does not respond to 1 capsule, 2 capsules may be used do not exceed 6 capsules in 24 hours, unless directed by a doctor Children under 12 years: ask a doctor

**Other information**

each capsule contains potassium 20 mg

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

**DISTRIBUTED BY THE KROGER CO., CINCINNATI, OHIO 45202  
MADE IN INDIA**

**OUR PHARMACIST RECOMMENDED**

7001 0324

LOT:  
EXP.:

Varnish Omit Area

Varnish/Print Omit Area

NDC 41226-700-80

**Kroger** health

**Ibuprofen**

Solubilized Ibuprofen Capsules 200 mg

**MINIS**  
SMALLER SOFTGEL  
SAME STRENGTH

**PAIN RELIEVER/  
FEVER REDUCER (NSAID)**

**80 SOFTGELS**

LIQUID-FILLED CAPSULES

ACTUAL SIZE

COMPARE TO THE ACTIVE INGREDIENT IN ADVIL® LIQUID-GELS® MINIS higher if you:

**Drug Facts (continued)**

**Warnings**

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.

**Drug Facts (continued)**

**When using this product**

Stop use and ask a doctor if you have any of the following symptoms:

- stomach pain that does not get better
- heartburn
- black or bloody stools
- feeling dizzy or lightheaded
- swelling in one part or side of the body
- chest pain
- trouble breathing
- fever gets worse or lasts more than 3 days
- fever gets worse or lasts more than 10 days
- itchiness or swelling is present in the painful area

**Other information**

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**Drug Facts (continued)**

**Directions**

do not take more than directed the smallest effective dose should be used adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist if pain or fever does not respond to 1 capsule, 2 capsules may be used do not exceed 6 capsules in 24 hours, unless directed by a doctor Children under 12 years: ask a doctor

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LOT:  
EXP.:

**Kroger** health

**Ibuprofen**

Solubilized Ibuprofen Capsules 200 mg

**MINIS**  
SMALLER SOFTGEL  
SAME STRENGTH

Varnish Omit

Varnish Omit

LOT:  
EXP.:



NDC 41226-700-66

**Kroger** health

# Ibuprofen

Solubilized Ibuprofen Capsules 200 mg

**MINIS**  
SMALLER SOFTGEL  
SAME STRENGTH

**LIQUID-FILLED CAPSULES**

**DO NOT USE IF SEAL UNDER BOTTLE CAP IMPRINTED WITH "SEALED FOR YOUR PROTECTION" IS BROKEN OR MISSING**

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

**160 SOFTGELS<sup>†</sup>**

**PAIN RELIEVER/  
FEVER REDUCER (NSAID)<sup>\*</sup>**

**Uses**

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

**Warnings**

**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 redness, rash, blisters. If an allergic reaction occurs, stop use and seek medical help right away.

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- children under 12 years: ask a doctor

**Other information**

- each capsule contains: potassium 20 mg
- Questions or comments? Call 1-800-632-6900

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**MADE IN INDIA**

**\*YOUR PHARMACIST RECOMMENDED**

LOT:  
EXP:

Varnish Coat Area

Coating/  
Print Omit Area

**Kroger** health

# Ibuprofen

Solubilized Ibuprofen Capsules 200 mg

**MINIS**  
SMALLER SOFTGEL  
SAME STRENGTH

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

**Drug Facts (continued)**

**Do not use**

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

**Ask a doctor before use if**

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- you have a history of stomach problems, such as heartburn
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- 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
  - fever gets worse or lasts more than 3 days
  - redness or swelling is present in the painful area
  - any new symptoms appear

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**Drug Facts (continued)**

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**Other information**

- each capsule contains: potassium 20 mg
- read all warnings and directions before use
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)

**Inactive ingredients**

ammonium hydroxide, FD&C green no. 3, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, potassium hydroxide, propylene glycol, purified water, shellac, sorbitan monooleate, sorbitol, sorbitan

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

Not all ingredients listed if there are 160 Softgels. Some 160 Softgels will contain 20 mg of potassium. See the Carton, Lot Mark, or Impression on the Carton for details. See Carton, Lot Mark, or Impression on the Carton for details. Lot Mark, Impression on the Carton, or Impression on the Carton.

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

**MADE IN INDIA**

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

**\*YOUR PHARMACIST RECOMMENDED**

7001 0204

**COMPARE TO THE ACTIVE INGREDIENT IN ADVIL® LIQUID-GELS\* MINIS**

**ACTUAL SIZE**

**320 SOFTGELS<sup>†</sup>**  
**2 BOTTLES -**  
**160 SOFTGELS<sup>†</sup> EACH**

**PAIN RELIEVER/  
FEVER REDUCER  
(NSAID)<sup>\*</sup>**

**LIQUID-FILLED CAPSULES**

**Kroger** health

# Ibuprofen

Solubilized Ibuprofen Capsules 200 mg

**MINIS**  
SMALLER SOFTGEL  
SAME STRENGTH

**LIQUID-FILLED CAPSULES**

**PAIN RELIEVER/  
FEVER REDUCER  
(NSAID)<sup>\*</sup>**

**320 SOFTGELS<sup>†</sup>**  
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LOT:  
EXP:

Coating/Print Omit Area

<b>IBUPROFEN</b> ibuprofen capsule, liquid filled			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:41226-700
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
<b>Ingredient Name</b>		<b>Basis of Strength</b>	<b>Strength</b>

<b>IBUPROFEN</b> (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
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### Inactive Ingredients

Ingredient Name	Strength
<b>AMMONIA</b> (UNII: 5138Q19F1X)	
<b>SORBITAN MONOOLEATE</b> (UNII: 06XEA2VD56)	
<b>MEDIUM-CHAIN TRIGLYCERIDES</b> (UNII: C9H2L21V7U)	
<b>FD&amp;C GREEN NO. 3</b> (UNII: 3P3ONR6O1S)	
<b>SHELLAC</b> (UNII: 46N107B71O)	
<b>POTASSIUM HYDROXIDE</b> (UNII: WZH3C48M4T)	
<b>GELATIN</b> (UNII: 2G86QN327L)	
<b>PROPYLENE GLYCOL</b> (UNII: 6DC9Q167V3)	
<b>WATER</b> (UNII: 059QF0KO0R)	
<b>FERROUS OXIDE</b> (UNII: G7036X8B5H)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	
<b>SORBITOL</b> (UNII: 506T60A25R)	

### Product Characteristics

<b>Color</b>	green	<b>Score</b>	no score
<b>Shape</b>	CAPSULE	<b>Size</b>	13mm
<b>Flavor</b>		<b>Imprint Code</b>	62
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-700-87	2 in 1 CARTON	04/15/2024	
1		160 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41226-700-80	1 in 1 CARTON	04/15/2024	
2		80 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	ANDA079205	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(41226-700)

Revised: 4/2024

KROGER COMPANY