

IBUPROFEN- ibuprofen tablet, coated
Kroger Company

600R Kroger 41226 600 Ibuprofen Tablets USP 200 mg (Brown Caplet)

DRUG FACTS

Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Uses

temporarily relieves minor aches and pains due to:

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

temporarily reduces fever

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin.

Symptoms may include:

- asthma (wheezing)
- blisters
- facial swelling
- hives
- rash
- shock
- skin reddening

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 ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- you have problems or serious side effects from taking pain relievers or fever reducers
- stomach bleeding warning applies to you
- 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

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

chest pain

trouble breathing

weakness in one part or side of the 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 the 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 caplet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 caplet, 2 caplets may be used
- do not exceed 6 caplets in 24 hours, unless directed by a doctor

children under 12 years:

- ask a doctor

OTHER INFORMATION

Other information

- read all warnings and directions before use
- store at 20-25°C (68-77°F)

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

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

COMPARE TO the active ingredient of
ADVIL® IBUPROFEN CAPLETS* See back panel



NDC 41226-600-50



Ibuprofen

Tablets USP, 200 mg
Pain Reliever/
Fever Reducer
(NSAID)

actual
size

500 COATED
CAPLETS†

(†CAPSULE-SHAPED TABLET)

**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) Purpose

Ibuprofen 200 mg (NSAID)* Pain reliever/Fever reducer
*nonsteroidal anti-inflammatory drug

Uses

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

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:

- asthma (wheezing)
- hives
- rash
- shock
- skin reddening
- blisters
- facial swelling

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

Drug Facts (continued under label)

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

*Ibuprofen is a registered trademark of Dow Chemical Company. Consumer Healthcare Holdings (S) LLC, Wilmington, DE 19806
Consumer Healthcare Holdings (S) LLC is not affiliated with The Kroger Co. or this product.

FOR MORE PRODUCT INFORMATION, SCAN UPC

USING YOUR KROGER APP
OR CALL 800-632-6900

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Love It or Your Money Back.

www.kroger.com

40125762 Code No. 600RUS515

Lot No.: 01302

Exp. Date:

Varnish Omit Area



Drug Facts (continued)

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 ibuprofen or any other pain reliever/fever reducer. **Do not use** if you have had an allergic reaction to ibuprofen or any other pain reliever/fever reducer. **Do not use** if you have had an allergic reaction to ibuprofen or any other pain reliever/fever reducer. **Do not use** if you have had an allergic reaction to ibuprofen or any other pain reliever/fever reducer.

Ask a doctor before use if you have problems or serious side effects from taking pain relievers or fever reducers. **Ask a doctor before use if** you have a history of stomach problems, such as heartburn. **Ask a doctor before use if** you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or had a stroke. **Ask a doctor before use if** you are taking a diuretic.

Ask a doctor or pharmacist before use if you are taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin. **Ask a doctor or pharmacist before use if you are** 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 problem or stroke: chest pain, trouble breathing, weakness in one part or side of the body, slurred speech, leg swelling
- rain 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. **Directions** do not take more than directed. **Directions** do not take more than directed. **Directions** do not take more than directed.

adults and children 12 years and over:

- take 1 caplet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 caplet, 2 caplets may be used
- do not exceed 6 caplets in 24 hours, unless directed by a doctor

children under 12 years:

- ask a doctor

Other information read all warnings and directions before use. **Other information** read all warnings and directions before use. **Other information** read all warnings and directions before use. **Other information** read all warnings and directions before use.

Inactive ingredients colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide.

Questions or comments? 1-800-632-6900

Adhesive Area

NDC 41226-600-01

Ibuprofen

Tablets USP, 200 mg
Pain Reliever/
Fever Reducer
(NSAID)

100 COATED
CAPLETS†

(†CAPSULE-SHAPED TABLET)

READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THE BOX FOR IMPORTANT INFORMATION.

Uses temporarily relieves minor aches and pains due to:

- backache
- headache
- menstrual cramps
- muscular aches
- the common cold
- toothache

Warnings temporarily relieves minor aches and pains due to:

- backache
- headache
- menstrual cramps
- muscular aches
- the common cold
- toothache

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Questions or comments? 1-800-632-6900

Varnish Omit Area

Lot No.:
Exp Date:

Exp. Date:
Lot No.:

0 4 1 2 6 0 0 1 3 0 3 4
12-digit UPC-A
(For Position Only)
89% SIZE

DISTRIBUTED BY THE KROGER CO.
CINCINNATI, OHIO 45202
600R 0622
MADE IN INDIA
For More Product Information,
Scan UPC Using Your Kroger App
or Call 800-632-6900

READ ALL PRODUCT INFORMATION BEFORE USING.
KEEP THE BOX FOR IMPORTANT INFORMATION.

Drug Facts

Active ingredient (in each caplet) Purpose
ibuprofen
200 mg (NSAID)*, Pain reliever/Fever reducer
*nonsteroidal anti-inflammatory drug

Uses

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

Warnings

- Allergy alert:** Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
- asthma (wheezing)
 - hives
 - rash
 - shock
 - skin reddening
 - blisters
 - facial swelling
 - skin reddening
- 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

Drug Facts (continued)

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 ibuprofen or any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

- you have problems or serious side effects from taking pain relievers or fever reducers
- stomach bleeding warning applies to you
- 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

- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- 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 problem or stroke:
 - chest pain
 - trouble breathing

Drug Facts (continued)

- 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 caplet every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 caplet, 2 caplets may be used
- do not exceed 6 caplets in 24 hours, unless directed by a doctor

children under 12 years:

- ask a doctor

Other information

- read all warnings and directions before use
- store at 20-25°C (68-77°F)

Coating
Omit

RECOMMENDED
OUR PHARMACIST

100 COATED CAPLETS*
(CAPSULE-SHAPED TABLET)

actual size

Ibuprofen
Tablets USP, 200 mg
Pain Reliever/
Fever Reducer
(NSAID)

Kroger

COMPARE TO the active ingredient of
ADVIL® IBUPROFEN CAPLETS *See side panel

NDC 41226-400-01

E827R1

Coating/Print Omit Area

Coating
Omit

Drug Facts (continued)

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments? 1-800-632-6900

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

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NDC 41226-600-42

Ibuprofen

Tablets USP, 200 mg
Pain Reliever/
Fever Reducer
(NSAID)

24
COATED
CAPLETS[†]

([†]Capsule-Shaped Tablet)

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

READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THE BOX FOR IMPORTANT INFORMATION.

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

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ asthma (wheezing) ■ blisters ■ facial swelling ■ hives ■ rash ■ shock ■ skin reddening. 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

Drug Facts (continued under label)

40125502 Code No.: G01DRUGS/515

Lot No.:

Varnish Omit Area

Exp. Date:



Drug Facts

 (continued)

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 ibuprofen or any other pain reliever/fever reducer ■ right before or after heart surgery

Ask a doctor before use if

■ you have problems or serious side effects from taking pain relievers or fever reducers ■ stomach bleeding warning applies to you ■ 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

Directions ■ do not take more than directed ■ the smallest effective dose should be used

adults and children 12 years and over:

■ take 1 caplet every 4 to 6 hours while symptoms persist

■ if pain or fever does not respond to 1 caplet, 2 caplets may be used

■ do not exceed 6 caplets in 24 hours, unless directed by a doctor

children under 12 years: ■ ask a doctor unless directed by a doctor

DISTRIBUTED BY THE KROGER CO.

CINCINNATI, OHIO 45202

MADE IN INDIA

FOR MORE PRODUCT INFORMATION,

SCAN UPC USING YOUR KROGER

APP OR CALL 800-632-6900

60QR 0622

Adhesive Area

READ ALL PRODUCT INFORMATION BEFORE USING. KEEP THE BOX FOR IMPORTANT INFORMATION.

Drug Facts

Active ingredient (in each caplet) Purpose
Ibuprofen 200 mg (NSAID)* Pain reliever/fever reducer
*nonsteroidal anti-inflammatory drug

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

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ● asthma (wheezing) ● hives ● facial swelling ● hives ● rash ● shock ■ skin reddening, if an allergic reaction occurs, stop use and seek medical help right away.
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Drug Facts (continued)

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 ibuprofen or any other pain reliever/fever reducer ■ fight before or after heart surgery

Ask a doctor before use if ■ you have problems or serious side effects from taking pain relievers or fever reducers ■ stomach bleeding warning applies to you ■ 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 ■ taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin ■ under a doctor's care for any serious condition ■ taking any other drug

When using this product ■ take with food or milk if stomach upset occurs ■ 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 blood or black stools ● have stomach pain that does not get better



Varnish Omit
Lot No.:
Exp Date:

DIST. BY THE KROGER CO., CINCINNATI, OHIO 45202
MADE IN INDIA
FOR MORE PRODUCT INFORMATION, SCAN UPC USING YOUR KROGER APP OR CALL 800-632-6900

Advil is a registered trademark of GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, Wilmington, DE 19808. GlaxoSmithKline Consumer Healthcare Holdings (US) LLC is not affiliated with The Kroger Co. or this product.

Drug Facts (continued)

■ you have symptoms of heart problem 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 caplet every 4 to 6 hours while symptoms persist ■ if pain or fever does not respond to 1 caplet, 2 caplets may be used ■ do not exceed 6 caplets in 24 hours, unless directed by a doctor

children under 12 years: ■ ask a doctor

Other information ■ read all warnings and

600R
0622

COMPARE TO the active ingredient of
ADVIL® IBUPROFEN CAPLETS *See side panel

NDC 41226-600-42



Ibuprofen
Tablets USP, 200 mg
Pain Reliever/Fever Reducer
(NSAID)



actual size
24 COATED CAPLETS*
(*Capsule-Shaped Tablet)

Varnish Omit

Varnish Omit

Varnish/Print Omit Area

IBUPROFEN

ibuprofen tablet, coated

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:41226-600
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
CROSCARMELLOSE SODIUM (UNII: M28OL1HH48)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	brown	Score	no score
Shape	CAPSULE (biconvex, film coated tablets)	Size	15mm
Flavor		Imprint Code	117
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:41226-600-01	1 in 1 CARTON	06/12/2021	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:41226-600-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	06/12/2021	
3	NDC:41226-600-42	1 in 1 CARTON	06/12/2021	
3		24 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	ANDA091239	06/12/2021	

Labeler - Kroger Company (006999528)

Registrant - TIME CAP LABORATORIES, INC. (037052099)

Establishment

Name	Address	ID/FEI	Business Operations
MARKSANS PHARMA LIMITED		925822975	manufacture(41226-600)

Revised: 12/2023

Kroger Company