

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

NDC 41226-600-01

Kroger health

Ibuprofen
Tablets USP, 200 mg

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

100 COATED CAPLETS[†]
1 CAPSULE-SHAPED TABLETS

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. 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.**

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

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

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

600R 0624

LOT:

EXP.:

Varnish Omit Area

Varnish/Print Omit Area

NDC 41226-600-01



COMPARE TO THE ACTIVE INGREDIENT IN ADVIL® CAPLETS*

Ibuprofen

Tablets USP, 200 mg

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

100 COATED CAPLETS*
*CAPSULE-SHAPED TABLETS



ACTUAL SIZE

Varnish Omit

Front of Package

Varnish Omit

Bottom of Package

REMAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT 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:
 - headache
 - toothache
 - muscular cramps
 - muscular aches
 - temporarily reduces fever

Warnings

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

- hives
- swelling of the face, lips, tongue, or throat
- skin redness, rash, or 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

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 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
- you have a history of stomach problems, such as heartburn
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma, or have a stomach 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 the benefit of aspirin
- taking any other drug

When using this product:

- take with food or milk if stomach upset occurs
- you experience any of the following signs of stomach bleeding:
 - feeling faint
 - vomit blood
 - have stomach pain that does not get better

Stop use and ask a doctor if:

- you experience any of the following signs of stomach bleeding:
 - feeling faint
 - vomit blood
 - 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

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

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YOUR PHARMACIST RECOMMENDED
600R 0624

Top of Package

Drug Facts (continued)

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 envelope size 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)

Inactive ingredients:

coloidal silicon dioxide, croscarmellose sodium, iron oxide red, magnesium stearate, microcrystalline cellulose, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, xite, titanium dioxide

Questions or comments? Call 1-800-432-4800

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LOT:
EXP.:
Varnish Omit

Side of Package



NDC 41226-600-42

Ibuprofen

Tablets USP, 200 mg

**PAIN RELIEVER/
FEVER REDUCER
[NSAID]***

**24 COATED
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

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

Drug Facts (continued under label)

LOT:

EXP.:



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

Keep out of reach of children.

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)

Questions or comments?

Call 1-800-632-6900

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MADE IN INDIA

6008 0624

Adhesive Area

E826R

Varnish/Print Omit Area

41226-600-42



COMPARE TO THE ACTIVE INGREDIENT IN ADVIL® CAPLETS*

Ibuprofen

Tablets USP, 200 mg

**PAIN RELIEVER/
FEVER REDUCER
[NSAID]**

**24 COATED CAPLETS*
'CAPSULE-SHAPED TABLETS'**

ACTUAL SIZE



Varnish Omit

Varnish Omit

RETAIN CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Drug Facts

Active ingredient (in each caplet): Ibuprofen 200 mg (NSAID)*
Purpose: Nonsteroidal anti-inflammatory drug

Uses

- Temporarily relieves minor aches and pains due to:
 - headaches
 - 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)
 - stitch
 - skin redness
 - rash
 - itching
- Stop use and seek medical help right away, if an allergic reaction occurs, stop use and seek medical help right away.
- Stomach bleeding warning:** This product contains an NSAID, which may cause serious 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 2 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 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 or heart blood or stroke, disease
- ibuprofen may decrease this benefit of aspirin
- 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:
 - red or black stool
 - dark or bloody or black stool
 - have stomach pain that does not get better
- you have symptoms of heart problems or stroke:
 - chest pain
 - trouble breathing

Other information:

- Contains inactive ingredients: stearic acid, croscarmellose sodium, iron oxide red, titanium dioxide

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 tablets 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)

Inactive ingredients: croscarmellose sodium, croscarmellose sodium, iron oxide red, titanium dioxide

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

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 *Asking your doctor or pharmacist about the health benefits of ibuprofen is important. For more information, visit www.kroger.com

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Drug Facts (continued)
 stearic acid, croscarmellose sodium, polyethylene glycol, polyvinyl alcohol, pregelatinized starch, talc, titanium dioxide

Questions or comments?
 Call 1-800-532-6900

LOT:
 EXP:
 0 41260 01294 5

Varnish Omit

NDC 41226-600-50

COMPARE TO THE ACTIVE INGREDIENT IN ADVIL® CAPLETS!

Ibuprofen

TABLETS USP, 200 mg ACTUAL SIZE

PAIN RELIEVER/ FEVER REDUCER (NSAID)*

500 COATED 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

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:
 - 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

Drug Facts (continued under label)

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YOUR PHARMACIST RECOMMENDED

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LOT: 41260101302

EXP:

Varnish Omit Area

PEEL HERE

Drug Facts (continued under label)

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

Ask a doctor before use if right before or after heart surgery

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
 - wornit 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 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)

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? Call 1-800-632-6900

Adhesive 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)