

IBUPROFEN- ibuprofen tablet, coated
CHAIN DRUG MARKETING ASSOCIATION INC

QCH-1112C-2020-0713

Drug Facts

Active ingredient (in each caplet)

Ibuprofen 200 mg (NSAID)*

* nonsteroidal anti-inflammatory drug

Purposes

Pain reliever/fever reducer

Uses

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

chances are 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
- the 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 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 during the last 3 months of 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)
- avoid high humidity and excessive heat above 40°C (104°F)
- retain carton for complete product information and warnings

Inactive ingredients

colloidal silicon dioxide, corn starch, FD&C yellow #6, polyethylene glycol, polyvinyl alcohol, povidone, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

PRINCIPAL DISPLAY PANEL

NDC 63868-570-50

Quality Choice®

†Compare to Active Ingredient in MOTRIN® IB

Ibuprofen

Ibuprofen Tablets, 200mg

Pain Reliever,

Fever Reducer (NSAID_

Actual Size

50 COATED CAPLETS**

**Capsule-Shaped Tablets

INK AND COATING FREE
FOR LOT AND
EXPIRATION STAMPING



DO NOT USE IF IMPRINTED SEAL
UNDER CAP IS BROKEN OR MISSING

† This product is not manufactured, distributed or Motrin® IB.
by participating or participating distributor of Motrin® IB.

Drug Facts

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

Uses ■ temporarily relieves minor aches
and pains due to: ■ headache
■ muscular aches ■ minor pain of arthritis
■ toothache ■ backache
■ the common cold ■ menstrual cramps
■ 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)
■ stomach ■ skin redness
■ 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 chances are 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
■ the 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
■ you experience any of the following signs of
stomach bleeding: ■ 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

Stop use and ask a doctor if

■ you experience any of the following signs of
stomach bleeding: ■ 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

Drug Facts (continued)

■ 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 during the last 3 months of
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

■ the smallest effective dose should be used

adults and
children 12 years
and older

■ 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

Other information

■ read all warnings and directions before use
■ store at 20°-25°C (68°-77°F)
■ avoid high humidity and excessive heat above
40°C (104°F)
■ retain carton for complete product information
and warnings



NDC 63868-570-50

*Compare to
Active Ingredient
in MOTRIN® IB

Ibuprofen

Ibuprofen Tablets, 200mg

Pain Reliever,
Fever Reducer (NSAID)

Actual Size



50 COATED CAPLETS**

**Capsule-Shaped Tablets

100% SATISFACTION
GUARANTEED
Distributed by C.D.M.A., Inc.®
Novi, MI 48375
43157 W 9 Mile Rd
Questions: 800-935-2362
Made in India
www.qualitychoice.com

Drug Facts (continued)
Inactive Ingredients
colloidal silicon dioxide, corn starch, FD&C
yellow #6, polyethylene glycol, polyvinyl alcohol,
glycolate, stearic acid, talc, titanium dioxide

IBUPROFEN

ibuprofen tablet, coated

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:63868-570

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)				
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)				
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)				
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)				
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)				
STARCH, PREGELATINIZED CORN (UNII: O8232NY3SJ)				
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)				
STEARIC ACID (UNII: 4ELV7Z65AP)				
TALC (UNII: 7SEV7J4R1U)				
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)				
Product Characteristics				
Color	orange	Score	no score	
Shape	OVAL	Size	14mm	
Flavor		Imprint Code	G2	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63868-570-50	1 in 1 CARTON	03/25/2020	10/31/2026
1		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:63868-570-01	1 in 1 CARTON	05/15/2020	04/30/2027
2		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category	Application Number or Monograph Citation		Marketing Start Date	Marketing End Date
ANDA	ANDA202312		03/25/2020	04/30/2027

Labeler - CHAIN DRUG MARKETING ASSOCIATION INC (011920774)

