

IBUPROFEN- ibuprofen tablet, film coated
Publix Super Markets Inc

Publix Super Markets, Inc. Ibuprofen Caplets 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 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 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

Children under 12 years: ask a doctor

Other information

- read all warnings and directions before use
- store between 68-77°F (20-25°C)
- avoid high humidity and excessive heat above 104°F (40°C)
- see end panel for lot number and expiration date

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, iron oxide red, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, polysorbate 80, stearic acid, titanium dioxide

Principal Display Panel

SEE REVISED WARNING

P

ibuprofen caplets**

IBUPROFEN TABLETS, 200 mg

PAIN RELIEVER/FEVER REDUCER (NSAID)

ACTUAL SIZE

50 COATED CAPLETS**

**CAPSULE-SHAPED TABLETS

Compare to Advil® active ingredient

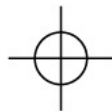
64771 63 C10

0 41415 15073 7



Important: Read all product information before using. Keep this box for important information. DO NOT USE IF PRINTED SEAL UNDER CAP IS BROKEN OR MISSING

ACTUAL SIZE



ibuprofen caplets**
IBUPROFEN TABLETS, 200 mg
PAIN RELIEVER/FEVER REDUCER (NSAID)
NDC 56062-647-71
50 COATED CAPLETS**
**CAPSULE-SHAPED TABLETS

Drug Facts

Active ingredient (in each caplet) **Purpose**
Ibuprofen 200 mg (NSAID)* Pain reliever/fever reducer
Hydrocortisone 10 mg (steroid) Pain reliever/fever reducer

Uses ■ temporarily relieve minor aches and pains due to:
■ muscle aches ■ minor pain of arthritis ■ toothache
■ headache ■ the common cold ■ menstrual cramps ■ temporarily reduce 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 pain ■ difficulty breathing ■ chest pain ■ trouble breathing ■ weakness in one part of the body ■ slurred speech ■ fever ■ get worse or lasts more than 3 days ■ redness or swelling present in the painful area ■ any new symptoms appear

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 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:

Drug Facts (continued)

asker turn ■ you have high blood pressure, heart disease, liver disease, kidney disease, asthma, or had a stroke ■ you are taking a diuretic

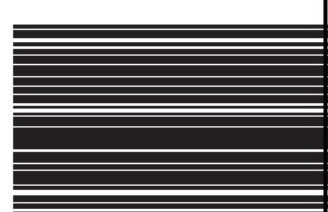
Ask a doctor or pharmacist before use if you are ■ taking aspirin for heart attack or stroke, because ibuprofen may decrease the benefit of aspirin ■ under a doctor's care for any serious condition ■ taking any other drug

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 of the body ■ slurred speech ■ fever ■ get worse or lasts more than 3 days ■ redness or swelling 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 a health professional tells you to do so, 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 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 ■ children under 12 years: ask a doctor

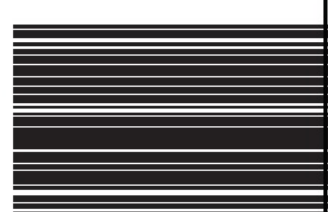


NDC 56062-647-71
SEE REVISED WARNING

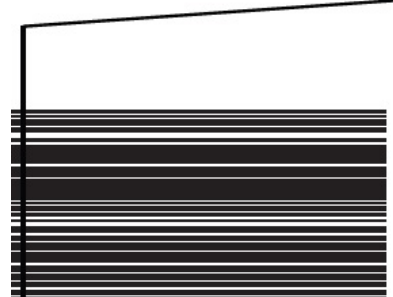
ibuprofen caplets**
IBUPROFEN TABLETS, 200 mg
PAIN RELIEVER/FEVER REDUCER (NSAID)



50 COATED CAPLETS**
**CAPSULE-SHAPED TABLETS
ACTUAL SIZE
Compare to Advil® active ingredient***



Drug Facts (continued)
■ sore to wear ■ read all warnings and directions before use ■ avoid high humidity and excessive heat above 104°F (40°C) ■ see end panel for lot number and expiration date
Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, hydroxypropyl methylcellulose, polyethylene glycol, polyorbital, iron oxide yellow, microcrystalline cellulose, polyethylene glycol, polyorbital, stearic acid, titanium dioxide
*****This product is not manufactured or distributed by GSKCH, distributor of Advil®.**
DISTRIBUTED BY PUBLIX SUPER MARKETS, INC.,
3300 PUBLIX CORPORATE PARKWAY, LAKELAND, FL 33811
1-888-267-3037 publix.com
PUBLIX GUARANTEE:
COMPLETE SATISFACTION OR YOUR MONEY BACK



IBUPROFEN
ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:56062-647
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)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics

Color	BROWN	Score	no score
Shape	OVAL	Size	15mm
Flavor		Imprint Code	I2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:56062-647-71	1 in 1 CARTON	01/31/2002	
1		50 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:56062-647-78	1 in 1 CARTON	09/15/1988	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:56062-647-85	1 in 1 CARTON	03/20/2000	
3		250 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	ANDA072096	09/15/1988	

Labeler - Publix Super Markets Inc (006922009)

Revised: 8/2023

Publix Super Markets Inc