

IBUPROFEN- ibuprofen tablet, film coated
Cardinal Health 107, LLC

Ibuprofen Tablets USP, 200 mg

DRUG FACTS

ACTIVE INGREDIENT

(in each white tablet)

Ibuprofen USP, 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

PURPOSE

Pain reliever/fever reducer

USES

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

WARNINGS SECTION

Read all warnings and directions before use.

SEE NEW WARNINGS INFORMATION

This unit dose package is not child resistant and is intended for institutional use only.

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 a nonsteroidal anti-inflammatory drug (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 an 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 or kidney disease
- you are taking a diuretic
- you have asthma or had a stroke

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
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
 - you have symptoms of heart problems or stroke
 - chest pain
 - Slurred speech
 - Leg swelling
 - Trouble breathing
 - Weakness in one part or side of body
-
- 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 (1-800-222-1222) right away.

DIRECTIONS

- do not take more than directed
- the smallest effective dose must be used

DOSAGE & ADMINISTRATION SECTION

- Adults and children 12 years and over: take 1 tablet every 4 to 6 hours while symptoms persist
 - if pain or fever does not respond to 1 tablet, 2 tablets 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

STORAGE: Store between 20-25°C (68°-77°F); Avoid excessive heat 40C (104F)

TAMPER EVIDENT: DO NOT USE IF BLISTER IS TORN OR BROKEN

INACTIVE INGREDIENTS

corn starch, colloidal silicon dioxide, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, triacetin

Questions or comments?

Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

Distributed By:

Major® Pharmaceuticals

17177 N Laurel Park Dr., Suite 233

Livonia, MI 48152 USA

MFGD By LNK, Hauppauge, NY 11788

Distributed By:

Cardinal Health

Dublin, OH 43017

L3432333-10124

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Principal Display Panel

Ibuprofen Tablets, USP 200 mg.

Pain Reliever/Fever Reducer (NSAID)

10 Tablets



B27

NDC 55154-0669-0

**IBUPROFEN TABLETS, USP 200 mg
Pain Reliever/Fever Reducer (NSAID)**

10 TABLETS

Drug Facts

Active ingredient (in each white tablet)
Ibuprofen USP, 200 mg (NSAID)*

Purpose
Pain reliever/fever
reducer

*nonsteroidal anti-inflammatory drug

Inactive ingredients colloidal silicon dioxide, corn starch, hypromellose, lactose anhydrous, magnesium stearate, microcrystalline cellulose, polydextrose, polyethylene glycol, povidone, sodium starch glycolate, stearic acid, triacetin

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

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

STORAGE: Store between 20° - 25° C (68° - 77° F)
avoid excessive heat 40° C (104° F)

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only.
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.

TAMPER EVIDENT: DO NOT USE IF BLISTER IS TORN OR BROKEN

Questions or comments?
Call 1-800-426-9391 8:30 AM-4:00 PM ET, Monday-Friday

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Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include:
- rash - hives - shock - facial swelling - asthma (wheezing)
- blisters - 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: - take more or for a longer time than directed - take a blood thinning (anticoagulant) or steroid drug - have had stomach ulcers or bleeding problems - have 3 or more alcoholic drinks every day while using this product - take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others] - are age 60 or older
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 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 - you have problems or serious side effects from taking pain relievers or fever reducers
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 - have bloody or black stools - vomit blood - have stomach pain that does not get better- you have symptoms of heart problems or stroke - chest pain - slurred speech - leg swelling - trouble breathing - weakness in one part or side of body - 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

IBUPROFEN

ibuprofen tablet, film coated

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-0669(NDC:0904-7914)
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XY110QM) (IBUPROFEN - UNII:WK2XY110QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
STARCH, CORN (UNII: O8232NY3SJ)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	

HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)
LACTOSE, UNSPECIFIED FORM (UNII: J2B2A4N98G)
MAGNESIUM STEARATE (UNII: 70097M6I30)
POLYDEXTROSE (UNII: VH2XOU12IE)
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)
CROSPROVIDONE, UNSPECIFIED (UNII: 2S7830E561)
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)
STEARIC ACID (UNII: 4ELV7Z65AP)
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)
TRIACETIN (UNII: XHX3C3X673)

Product Characteristics

Color	WHITE	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	44;438
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-0669-0	10 in 1 BAG	06/03/2011	
1		1 in 1 BLISTER PACK; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA075139	06/03/2011	

Labeler - Cardinal Health 107, LLC (118546603)

Revised: 1/2024

Cardinal Health 107, LLC