

IBUPROFEN 200MG- ibuprofen tablet
Allegiant Health

381 - Ibuprofen 200mg Tablet

Active ingredient(s)

Ibuprofen USP, 200mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

Pain Reliever/Fever reducer

Use(s)

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

Ask a doctor or pharmacist before use if

- 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
- vomit blood
- have bloody or black stools
- have stomach pain that does not get better

Pregnancy/Breastfeeding

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 (1-800-222-1222) right away.

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

Other information

- store between 20-25 °C (68-77° F)
- read all warnings and directions before use
- do not use if seal under bottle cap is broken or missing

Inactive ingredients

colloidal silicon dioxide, corn starch, FD&C yellow #6, hypromellose, polydextrose, polyethylene glycol, povidone, pregelatinized starch, purified water, sodium starch glycolate, stearic acid, titanium dioxide

Questions

Call 1-888-952-0050 Monday through Friday 9AM - 5PM EST

Principal Display Panel

HealthA2Z®

SEE NEW WARNINGS
FAST RELIEF MEDICINE FOR PAIN

Ibuprofen

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

100 Tablets

SEE CARTON FOR COMPLETE INFORMATION

Uses: Ibuprofen temporarily relieves minor aches and pains due to:
■ headaches ■ toothaches ■ backaches ■ menstrual cramps ■ the common cold ■ muscular aches ■ minor pain of arthritis ■ temporarily reduces fever

Warnings:
Ibuprofen, like aspirin, may cause a severe allergic reaction, especially in people taking aspirin. Symptoms may include:
■ hives ■ facial swelling ■ asthma ■ wheezing ■ shock ■ skin redness ■ 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.

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

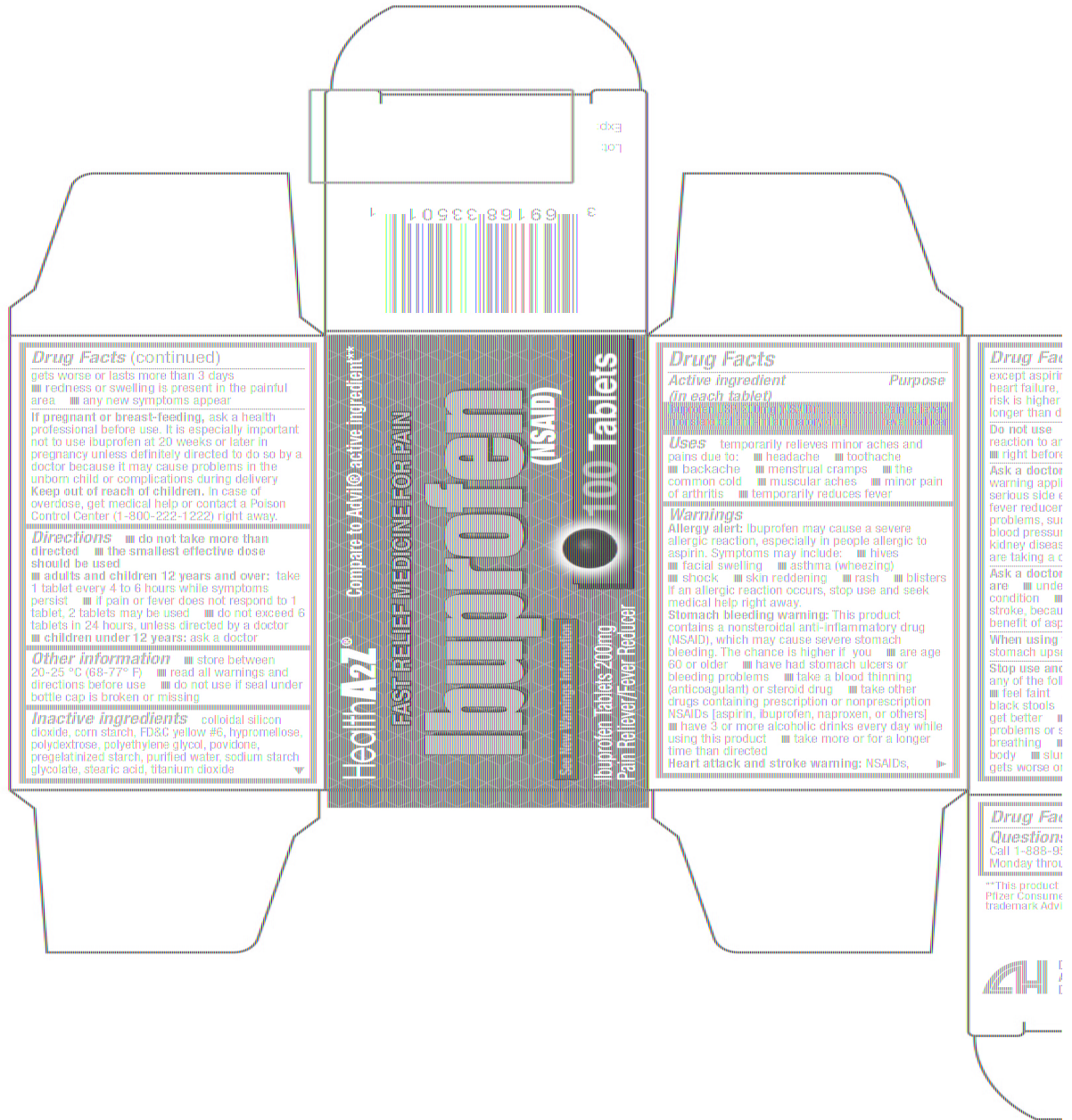
If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions: ■ do not take more than directed ■ the smallest effective dose 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

Distributed by:
AH Allegiant Health
Deer Park, NY 11729

LB1980
R1121

Ibuprofen label



Drug Facts (continued)

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 (1-800-222-1222) right away.

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

Other information ■ store between 20-25 °C (68-77° F) ■ read all warnings and directions before use ■ do not use if seal under bottle cap is broken or missing

Inactive ingredients colloidal silicon dioxide, corn starch, FD&C yellow #6, hypromellose, polydextrose, polyethylene glycol, povidone, pregelatinized starch, purified water, sodium starch glycolate, stearic acid, titanium dioxide

HealthAzz® Compare to Advil® active ingredient**

FAST RELIEF MEDICINE FOR PAIN

Ibuprofen (NSAID)

200mg Tablets

Ibuprofen Tablets 200mg Pain Reliever/Fever Reducer

See New Warnings Information

Drug Facts

Active ingredient (in each tablet)	Purpose
Ibuprofen 200mg	Temporarily relieves minor aches and pains due to:

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 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 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, ▶

Drug Facts

except aspirin heart failure, risk is higher longer than d

Do not use reaction to ar ■ right before

Ask a doctor warning appl serious side e

fever reducer problems, su blood pressu kidney diseas are taking a c

Ask a doctor are ■ unde condition ■ stroke, becau benefit of asp

When using stomach upst

Stop use anc any of the fol

■ feel faint ■ black stools ■ get better ■ problems or s ■ breathing ■ body ■ slur ■ gets worse or

Drug Facts

Question: Call 1-888-92 Monday thro

**This product, Pfizer Consumer trademark Advil



IBUPROFEN 200MG

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-381
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
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE, UNSPECIFIED (UNII: 3NXW29V3WO)	
POLYDEXTROSE (UNII: VH2XOU12IE)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POVIDONE (UNII: FZ989GH94E)	
WATER (UNII: 059QF0KO0R)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	brown	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	G2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-381-03	250 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2021	
2	NDC:69168-381-01	1 in 1 CARTON	11/16/2021	
2		100 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:69168-381-30	1 in 1 CARTON	11/16/2021	
3		30 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:69168-381-40	1 in 1 CARTON	11/16/2021	

4		40 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:69168-381-05	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/16/2021	
6	NDC:69168-381-32	100 in 1 BOTTLE; Type 0: Not a Combination Product	05/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	11/16/2021	

Labeler - Allegiant Health (079501930)

Revised: 11/2021

Allegiant Health