

IBUPROFEN FAST RELIEF MEDICINE FOR PAIN- ibuprofen 200 mg tablet
Allegiant Health

Drug Facts

Active ingredient (in each tablet)

Ibuprofen USP, 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 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, 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 you are

■ taking aspirin to prevent 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 the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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 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

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 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
- 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,

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.

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

Inactive Ingredients

corn starch, hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, pregelatinized starch, silicon dioxide, sodium starch glycolate, talc, titanium dioxide, triacetin

Package/Label Principal Display Panel

HealthA2Z®

Compare to Advil® active ingredient**

FAST RELIEF MEDICINE FOR PAIN

Ibuprofen

(NSAID)*

SEE NEW WARNINGS

Ibuprofen Tablets 200mg

Pain Reliever/Fever Reducer

(pill image)

Tablets

HealthA2Z
FAST RELIEF MEDICINE FOR PAIN
Ibuprofen (NSAID)
100 Tablets
Compare to Advil® active ingredient**
See New Warnings Information
Ibuprofen Tablets 200mg
Pain Reliever/Fever Reducer

Drug Facts (continued)
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
do not take longer than 10 days, unless directed by a doctor (see Warnings)

Adults and children 12 years and older
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 corn starch

Drug Facts
Active ingredient (in each tablet) Ibuprofen USP, 200mg (NSAID)* ...fever reducer *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 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.

Do not use if you have ever had an

Drug Facts (continued)
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 you are taking any other drug containing an NSAID (prescription or nonprescription), taking a blood thinning (anticoagulant) or steroid drug, 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, long term continuous use may increase the risk of heart attack or stroke
Stop use and ask a doctor if you feel faint, vomit blood, have bloody or black stools. These are signs of stomach bleeding, pain gets worse or lasts more than 10 days, fever gets worse or lasts more than 3 days, stomach pain or upset gets worse or lasts, redness or swelling is present in the painful area, any new symptoms appear
If pregnant or breast-feeding, ask a

Drug Facts (continued)
hypromellose, iron oxide red, magnesium stearate, microcrystalline cellulose, pregelatinized starch, silicon dioxide, sodium starch glycolate, talc, titanium dioxide, triacetin

Questions or Comments?
Call 1-888-952-0050
Monday through Friday 9AM – 5PM EST

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Allegiant Health
Deer Park, NY 11729
LB0870
R0416

Ibuprofen 200mg

IBUPROFEN FAST RELIEF MEDICINE FOR PAIN

ibuprofen 200 mg tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-335
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
STARCH, CORN (UNII: O8232NY3SJ)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A CORN (UNII: AG9B65PV6B)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TRIACETIN (UNII: XHX3C3X673)	

Product Characteristics

Color	BROWN	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	IBU200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-335-01	100 in 1 BOX; Type 0: Not a Combination Product	12/19/2014	
2	NDC:69168-335-03	250 in 1 BOTTLE; Type 0: Not a Combination Product	12/19/2014	
3	NDC:69168-335-30	30 in 1 BOX; Type 0: Not a Combination Product	12/19/2014	
4	NDC:69168-335-40	40 in 1 BOX; Type 0: Not a Combination Product	12/19/2014	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079129	12/19/2014	

Labeler - Allegiant Health (079501930)**Establishment**

Name	Address	ID/FEI	Business Operations
Strides Shasun Limited		871402375	ANALYSIS(69168-335) , MANUFACTURE(69168-335)