

**IBUPROFEN- ibuprofen tablet
Granules USA, Inc.**

SEE NEW WARNINGS

Ibuprofen

Tablets USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)**

Active ingredient (For Tablet)

(in each tablet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Active ingredient (For Caplet)

(in each caplet)

Ibuprofen 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purpose

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

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 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 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 the reach of children.

In case of overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

Directions (For Tablets)

- **do not take more than directed**

- **the smallest effective dose should be used**

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

Directions (For Caplets)

- **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

- store between 20-25°C (68-77°F). [See USP Controlled Temperature]

- avoid excessive heat above 40°C (104°F)

Inactive ingredients

colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone k-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide.

Questions or comments?

call **1-877-770-3183** weekdays 9:00 AM to 4:30PM EST.

Principal Display Panel

COATING
FREE AREA

R-00
537000018
300000427

Dulcinate
Dulcinate
38 Waverly Blvd., Jaffee
Pawnee, NJ 07054
MADE IN INDIA

This product is not manufactured
for distribution in the United States
by the manufacturer, distributor or dealer.

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13874-02022
3

size : 1+3/4 X 1+3/4 X 3+3/8	
ref # : PP180604B	
material : 016 SBS	

COATING
FREE AREA

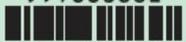
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R-00

COATING
FREE AREA

Principal Display Panel

ITEM NAME : 24000025	
Item :	BIG LOTS IBUPROFEN SOFT GEL
code # :	
size :	1+7/8 X 1+7/8 X 3+33/64
ref # :	PP181130A
material :	.016 SBS
view :	date

R-00
537000025
300000461



See New Warnings

GRANULES
CONSUMER HEALTH

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

100 Coated Tablets

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

See New Warnings

GRANULES
CONSUMER HEALTH

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

100 Coated Tablets

Contains no ingredient made from a gluten-containing grain (wheat, barley, or rye)

Actual Size

*Compares to the active ingredient in Advil®

Important: Read all the product information before using. Keep this box for important information.

DO NOT USE IF FOIL LINER SEAL IS BROKEN OR MISSING

Drug Facts (continued)

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**

Drug Facts (continued)

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 the 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

<p>adults and children 12 years and older</p> <ul style="list-style-type: none"> ■ 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 	<ul style="list-style-type: none"> ■ ask a doctor
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children under 12 years

Other information

- store between 20-25°C (68-77°F). (See USP Controlled Room Temperature).
- avoid excessive heat above 40°C (104°F)

Inactive ingredients colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone K-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide

Questions or comments?
call 1-877-776-3183 weekdays 9:00 AM to 4:30 PM EST

Drug Facts

Active ingredient (in each tablet) Purpose

Ibuprofen 200 mg _____ Pain reliever/fever reducer (NSAID)*

*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 severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: ■ hives ■ facial swelling ■ asthma (wheezing) ■ shock ■ skin reddening ■ rash ■ blisters

■ 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: ■ 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 ▶

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This product is not manufactured or distributed by Wyeth Consumer Healthcare, distributor of Advil®.

Distributed by: Granules Consumer Health
35 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054

MADE IN INDIA



8 13874 02031 5

Lot _____

Exp. _____

Principal Display Panel

size :1+3/4 X 1+3/4 X 3+3/8
 ref # :PP180604B
 material :.016 SBS

COATING
FREE AREA

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This product is not manufactured
or distributed by Pharm. Consumer
Healthcare, distributor of Advil®.
Pharm. Consumer
Healthcare, N.J. 07054
MADE IN INDIA

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

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

Drug Facts (continued)

- 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 the 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

- store between 20-25°C (68-77°F). (See USP Controlled Room Temperature).
- avoid excessive heat above 40°C (104°F)

Inactive ingredients colloidal silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone K-30, pregelatinized starch, sodium starch

See New Warnings

GRANULES
CONSUMER HEALTH

Ibuprofen

Tablets USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)*

24 Coated Caplets**

Actual Size

*Compare to the active ingredient in Advil®

**Compare to the active ingredient in Advil®

Contains no ingredients made from a gluten-containing grain (wheat, barley, or rye)

24 Coated Caplets (tablets)

Important: Read all the product information before using. Keep this box for important information.

DO NOT USE IF FOIL INNER SEAL IS BROKEN OR MISSING

Drug Facts

Active ingredient (in each caplet) Purpose
 Ibuprofen 200 mg Pain reliever/fever reducer (NSAID)
 *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 severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), shock, skin redness, rash, hives

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: 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

COATING
FREE AREA

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R-00

Drug Facts (continued)

glycolate, stearic acid, talc, titanium dioxide

Questions or comments?
 call 1-877-770-3183
 weekdays 9:00 AM to 4:30 PM EST

Lot

Exp.

COATING
FREE AREA

Principal Display Panel

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69848-012
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
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STARCH, CORN (UNII: O8232NY3SJ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	

Product Characteristics

Color	brown (Reddish Brown color Tablets)	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:69848-012-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	
2	NDC:69848-012-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	
3	NDC:69848-012-25	250 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	07/01/2019	

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69848-011
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)	
TALC (UNII: 7SEV7J4R1U)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
POVIDONE (UNII: FZ989GH94E)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STARCH, CORN (UNII: O8232NY3SJ)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	

Product Characteristics

Color	brown (Reddish Brown tablets)	Score	no score
Shape	OVAL (Caplet shaped Tablets)	Size	14mm
Flavor		Imprint Code	G2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69848-011-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2019	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	07/01/2019	

Labeler - Granules USA, Inc. (137098864)