

**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.

Tablets

1 3/4 1 3/4

DIE: PP180604E

PIONEER PKG	
end user :	GRANULES
item :	CVS APAP RR 50CT
code # :	
size :	1+3/4 X 1+3/4 X 3+3/8
ref # :	PP180604B
material :	.016 SBS
view	date

COATING FREE AREA

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300000427

0 13874 02022 3

This product has not been evaluated by the FDA for safety and effectiveness in children.

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
- if 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 the benefit of aspirin
- under a doctor's care for any serious condition
- taking any other drug

When using this product

- do not 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: • fast heart • 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 goes worse or lasts more than 10 days • fever goes worse or lasts more than 3 days • redness or swelling is present in the painful area

Drug Facts (continued)

Do not use

- if 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
- in 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

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, polydextrose K-30, pregelatinized starch, sodium starch

See New Warnings

GRANULES

CONSUMER HEALTH

Ibuprofen

Tablets USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)*

24 Coated Tablets

Actual Size

*Compare 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

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 reduce fever

Warnings

Always alert: Ibuprofen may cause severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: • hives • facial swelling • asthma (wheezing) • shock or skin redness as rash or 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 stroke 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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Drug Facts (continued)

glycolate, stearic acid, talc, titanium dioxide

Questions or comments?
call 1-877-776-3883
weekdays 8:00 AM to 4:20 PM EST

Lot

Exp.

COATING FREE AREA

3

end user : GRANULES
 item : 53700025 IBUPROFEN GRAY GRG
 code # :
 size : 11/7/8 X 11/7/8 X 3/33/64
 ref # : 19918130A view : PRINT STOR
 material : 016 888 date : 11/17/2019

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 300000461


Drug Facts (continued)
 Increases 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
 if 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
 if the stomach bleeding warning applies to you
 if you have a history of stomach problems, such as heartburn or you have high blood pressure, heart disease, liver cirrhosis, kidney disease, asthma or had a stroke
 if 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
 to 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: • red stool • vomit blood • have bloody or black stools • have stomach pain that does not get better
 if you have symptoms of heart problems or stroke: • chest pain • trouble breathing • weakness in one part or side of body • altered speech • leg swelling
 if pain gets worse or lasts more than 10 days or their pain comes or lasts more than 3 days
 if redness or swelling is present in the painful area
 if any new symptoms appear
 if pregnant or breast-feeding, ask a health professional ➤

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Drug Facts (continued)
 before use. It is especially important not to use ibuprofen during the last 3 months of pregnancy unless specifically directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.
 Stay out of the sun if you are taking ibuprofen, as it may increase your risk of sunburn.
Directions
 Do not take more than directed
 in 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
Other Information
 Store at controlled room temperature (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, croscellose H-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide
Quantity of Contents
 100 Coated Tablets
 call 1-877-776-4783 weekdays 9:00 AM to 4:30 PM EST

See New Warnings
IBUPROFEN
 CONSUMER HEALTH
Ibuprofen
 Tablets USP, 200 mg
 Pain Reliever/Fever Reducer (NSAID)
 Contains no aspirin made from a salmon-containing fish (avoid, see key info)
 100 Coated Tablets

See New Warnings
IBUPROFEN
 CONSUMER HEALTH
Ibuprofen
 Tablets USP, 200 mg
 Pain Reliever/Fever Reducer (NSAID)
 Contains no aspirin made from a salmon-containing fish (avoid, see key info)
 100 Coated Tablets

Actual Size
 Contains no aspirin made from a salmon-containing fish (avoid, see key info)

This product is not manufactured or distributed by Wyeth Consumer Healthcare, distributor of ASA®.
 Distributed by: Shionee Consumer Health
 26 Waterline Blvd., and Plaza, Parsippany, NJ 07054
 MADE IN INDIA

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 Lot
 Exp.

Important: Read all the printed information before using.
 Keep this box for important information
DO NOT USE IF FEEL EITHER SICK, OR BROKEN OR UNUSUAL

Drug Facts
Active Ingredient (in each tablet): Ibuprofen 200 mg
Purpose: Pain reliever/fever reducer (NSAID)
Indication: nonsteroidal anti-inflammatory drug
Uses
 temporarily relieve minor aches and pains due to:
 medicines or muscle aches in minor pain of arthritis
 headache or backache in the common cold
 menstrual cramps
 temporarily reduce fever
Warnings
 Allergy alert: Ibuprofen may cause severe allergic reactions, especially in people allergic to aspirin. Symptoms may include: hives or facial swelling or rashes (swelling) or shock or skin redness or rash in children
 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
 do not take stomach ulcers or bleeding problems
 do take a blood thinner (anticoagulant) or steroid drug
 do take other drugs containing prescription or nonprescription NSAIDs (aspirin, ibuprofen, naproxen, or others)
 do have 3 or more alcoholic drinks every day while using this product
 do take more or for a longer time than directed
 do not drink and drive warning: NSAIDs, except aspirin ➤

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Caplets



IBUPROFEN

ibuprofen tablet

Product Information

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: ETJ7Z6XB4U)	

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)