

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

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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 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
- if pain gets worse or lasts more than 10 days
- if fever gets worse or lasts more than 3 days
- if 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

Aspirin to the rescue! Ibuprofen to the rescue!

Actual Size

Drug Facts (continued)

glycolate, stearic acid, talc, titanium dioxide

Questions or comments?

call 1-877-776-3883

weekdays 9:00 AM to 4:30 PM EST

Lot

Exp.

COATING FREE AREA

3

**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**

Uses

- temporarily relieves minor aches and pains due to:
 - headaches ■ 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 or facial swelling or asthma (wheezing) or shock or skin reddening or rash or blisters. If an allergic reaction occurs, stop use and seek medical help right away.

NSAIDs, 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.

Heart attack and stroke warning: NSAIDs, except aspirin ►

See New Warnings

Ibuprofen

Tablets USP, 200 mg

Pain Reliever/Fever Reducer (NSAID)

Cytosine on lipopolymer made from a polyacrylate-hydrogel matrix. Ibuprofen, 200 mg.

Actual Size



100 Coated Tablets

[†]This product is not manufactured or distributed by Wyeth Consumer Healthcare, distributor of ActiV®.

Distributed by: Brenson Consumer Health
25 Wickliffe Blvd., 3rd Floor, Parsippany, NJ 07054
800-233-8888

Lot	Exp.	QTY	UNIT PRICE	TOTAL PRICE
1	1/25/2025	1	100.00	100.00
2	1/25/2025	1	100.00	100.00
3	1/25/2025	1	100.00	100.00
4	1/25/2025	1	100.00	100.00
5	1/25/2025	1	100.00	100.00
6	1/25/2025	1	100.00	100.00
7	1/25/2025	1	100.00	100.00
8	1/25/2025	1	100.00	100.00
9	1/25/2025	1	100.00	100.00
10	1/25/2025	1	100.00	100.00
11	1/25/2025	1	100.00	100.00
12	1/25/2025	1	100.00	100.00
13	1/25/2025	1	100.00	100.00
14	1/25/2025	1	100.00	100.00
15	1/25/2025	1	100.00	100.00
16	1/25/2025	1	100.00	100.00
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30	1/25/2025	1	100.00	100.00
31	1/25/2025	1	100.00	100.00
32	1/25/2025	1	100.00	100.00
33	1/25/2025	1	100.00	100.00
34	1/25/2025	1	100.00	100.00
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36	1/25/2025	1	100.00	100.00
37	1/25/2025	1	100.00	100.00
38	1/25/2025	1	100.00	100.00
39	1/25/2025	1	100.00	100.00
40	1/25/2025	1	100.00	100.00
41	1/25/2025	1	100.00	100.00
42	1/25/2025	1	100.00	100.00
43	1/25/2025	1	100.00	100.00
44	1/25/2025	1	100.00	100.00
45	1/25/2025	1	100.00	100.00
46	1/25/2025	1	100.00	100.00
47	1/25/2025	1	100.00	100.00
48	1/25/2025	1	100.00	100.00
49	1/25/2025	1	100.00	100.00
50	1/25/2025	1	100.00	100.00
51	1/25/2025	1	100.00	100.00
52	1/25/2025	1	100.00	100.00
53	1/25/2025	1	100.00	100.00
54	1/25/2025	1	100.00	100.00
55	1/25/2025	1	100.00	100.00
56	1/25/2025	1	100.00	100.00
57	1/25/2025	1	100.00	100.00
58	1/25/2025	1	100.00	100.00
59	1/25/2025	1	100.00	100.00
60	1/25/2025	1	100.00	100.00
61	1/25/2025	1	100.00	100.00
62	1/25/2025	1	100.00	100.00
63	1/25/2025	1	100.00	100.00
64	1/25/2025	1	100.00	100.00
65	1/25/2025	1	100.00	100.00
66	1/25/2025	1	100.00	100.00
67	1/25/			

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
- 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
- if 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
 if under a doctor's care for any serious condition
 if taking any other drug

When using this product
 in take with food or milk if stomach upset occurs

Stop now and ask a doctor if
 in you experience any of the following signs of stomach
 bleeding: a foul taste in your mouth, blood in your stool or black

Call your doctor if you have:

- chest pain or trouble breathing
- swelling in one part or side of body
- blurred speech
- leg swelling
- pain going down or back more than 10 days in fewer girls
- more than 3 days of redness or swelling in present in the painful area.

If pregnant or breast-feeding, ask a health professional ►

Drug Facts (continued)
before use. It is especially important not to use Isuprel 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

<p>adults and children 12 years and older</p>	<p>take 1 tablet every 4 to 6 hours while symptoms persist</p> <p>if pain or fever does not respond to 1 tablet, 2 tablets</p>
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	may be used
	do not exceed 8 tablets in 24 hours, unless directed by a doctor
children under	ask a doctor

12 years	
Other information	

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

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

call 1-877-776-8123 weekdays 9:00 AM to 4:30 PM EST

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R-00

8 13874 02031 5

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: 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)

Revised: 12/2023

Granules USA, Inc.