

IBUPROFEN- ibuprofen tablet
RETAIL BUSINESS SERVICES,LLC.

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

Active ingredient (in each tablet)

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

- **do not take more than directed**
- **the smallest effective dose should be used**

- 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

■ ask a doctor

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

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

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

[illegible]

ITEM	300000524	Guadipac
code #	1	
size	1+3/4 X 1+3/4 X 3+3/8	
ref #	P9180604B	vie
material	.016 SBS	dat

COATING FREE AREA

R-00
551000002
300000524

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: • red, black, or tarry stools • 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

COATING FREE 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 reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away. (1-800-422-4222)

Directions

- 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

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

THIS PRODUCT IS NOT MANUFACTURED OR DISTRIBUTED BY "WALTHAM CONSUMER HEALTHCARE, DISTRIBUTOR OF ADAPT".

5-2317 1219

3 41520 31045 4

For patient questions or concerns, contact your pharmacist or call 1-877-770-3183 weekdays 9:00 AM to 4:00 PM EST.

CAREONE

IBUPROFEN

200 mg

Tablets, USP

Pain Reliever/Fever Reducer NSAID

See New Warnings

24 COATED TABLETS

Actual Size

Compare to the Active Ingredient in Advil

Drug Facts (continued)

Questions or comments?

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

Lot

Exp.

COATING FREE AREA

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 tablet): Ibuprofen 200 mg. **Purpose:** Pain reliever/fever reducer (NSAID).

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - muscle aches
 - minor pain of arthritis
 - teethache
 - 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).

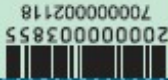
Check for skin redness, rash, or blisters.

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 thinner (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.

code #	:		vi
size	:	1+3/4 X 1+3/4 X 3+3/8	da
ref #	:	1991880040	
material	:	0.016 SBS	

COATING
FREE AREA



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 disease, kidney disease, asthma or had a stroke
- you are taking a diuretic

Ask a doctor or pharmacist before use if you are

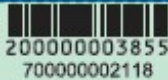
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- under a doctor's care for any serious condition
- taking any other drug

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: • 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 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



COATING
FREE AREA

Drug Facts (continued)

Keep these symptoms appear

If pregnant or breastfeeding, ask a health professional when use. It is especially important not to use ibuprofen of 30 weeks or later in pregnancy unless directed 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
- 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
- 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: croscellose, silicon dioxide, iron oxide red, maize starch, polyethylene glycol, povidone I-30, pregelatinized starch, sodium starch glycolate, stearic acid, talc, titanium dioxide



Contains no propylene glycol from a gluten-containing grain (barley, barley or rye)

100 COATED TABLETS



Tablets USP
200 mg

IBUPROFEN

Actual Size

CAREONE®

Compare to the Active Ingredient to Aid!

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

DO NOT USE IF SEAL UNDER THE CAP 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
- muscle aches
- minor pain of arthritis
- toothache
- backache
- the common cold
- menstrual cramps
- temporarily reduces fever

Warnings

Warning: Ibuprofen may cause a severe allergic reaction, especially in people allergic to aspirin. Symptoms may include: hives, facial swelling, asthma (wheezing), stomach pain, redness, rash, or dizziness. 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 thinner (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

Drug Facts (continued)

Questions or comments?

1-877-739-4789 Mon-Fri 8:00 AM (ET) to 5:00 PM (PST)

Lot

Exp.

COATING
FREE AREA



IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72476-365
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:72476-365-05	50 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	
2	NDC:72476-365-10	100 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	
3	NDC:72476-365-20	200 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	
4	NDC:72476-365-24	24 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	
5	NDC:72476-365-50	500 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	
6	NDC:72476-365-99	1000 in 1 BOTTLE; Type 0: Not a Combination Product	07/26/2020	
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA		ANDA079174	07/26/2020	

Labeler - RETAIL BUSINESS SERVICES,LLC. (967989935)

Revised: 12/2023

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