# IBUPROFEN- ibuprofen tablet RETAIL BUSINESS SERVICES,LLC.

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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

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

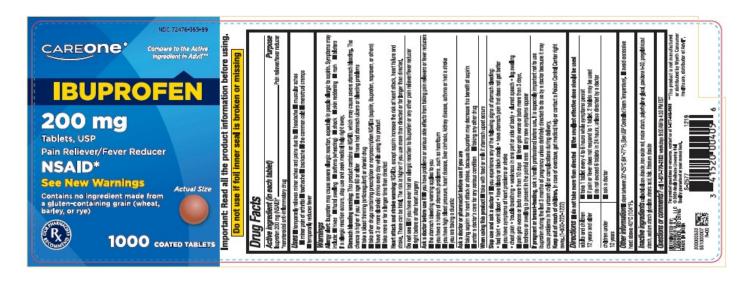
# **Inactive ingredients**

colloidal silicon dioxide, ferric 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.

### **PDP**





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### Drug Facts (continued)

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Pain Reliever/Fever Reducer N
See New Warnings
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glater-containing grain (wheat barley, or rys)

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NSAID\* 24

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TABLETS

Actual Size

Compare to the Active ingredient in Advir\*\*

NDC /2476-365-24

DO NOT USE IF FOIL INNER SEAL IS BROKEN OR MISSING Drug Facts

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size

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

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Active ingredient (in each tablet) Purpose \_Pain reflever/ fever reducer supraten 200 mg (NSAID)\*
\*nonstaroidal enti-inflammatory drug

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material :.016 SBS

#### Uses

Temporarily relieves minor ashes and pains due to:

| headache | muscular aches | minor pain of arthritis |
| teethache | backache | the common cold

temporarily reduces fever

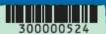
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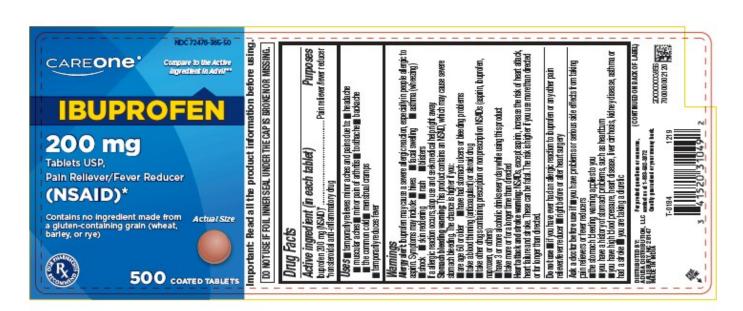
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Drug Facts (continued) Questions or comments?

ce 1-877-770-3183 weekdays 9:00 AM to 4:30 PM EST

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Other information ■ store between 20°-25°C (88°-77°P). [See USP bontooled Room Temperature]. ■ avoid excessive heat above 40°C (104°F)

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estrons or comments? 1-877-770-3183 Mon-Fri8:00AM EST to 5:00 PM PST



Other Information

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and exceeding heat above 40°C (104°F)

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Tablets USP,
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Drug Facts
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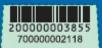
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Drug Facts (continued)

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Questions or comments? c#1-477-770-4180 No.-H & OLD REST IS SOUTHERST

Actual Size

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# **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

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII: WK2XYI10QM)

BUPROFEN (UNII: WK2XYI10QM) | BUPROFEN | 200 mg

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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			

P	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 RETAIL BUSINESS SERVICES,LLC.