

**IBUPROFEN- ibuprofen tablet**  
**Medline industries, LP**

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**674 Ibuprofen Tablets USP**

***Active ingredient (in each tablet)***

Ibuprofen UPS, 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

***Warnings***

**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 reach of children.**

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

**Directions**

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

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adults and children 12 years and older	<ul style="list-style-type: none"><li>• take 1 tablet every 4 to 6 hours while symptoms persist</li><li>• if pain or fever does not respond to 1 tablet, 2 tablets may be used</li><li>• do not exceed 6 tablets in 24 hours, unless directed by a doctor</li></ul>
children under 12 years	<ul style="list-style-type: none"><li>• ask a doctor</li></ul>

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**Other information**

- Store at 20°-25°C (68° to 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 1-877-770-3183 weekdays 9:00 AM to 4:30 PM EST

**Manufacturing Information**

Manufactured for:

Medline Industries, LP

Three Lakes Drive, Northfield, IL 60093 USA

Made in India

[www.medline.com](http://www.medline.com)

1-800-MEDLINE (633-5463)

REF: OTCM00020

V1 RE22GAE

Package Label

**Ibuprofen Tablets USP**  
Pain Reliever  
Fever Reducer  
(NSAID)\*

**200 mg**

**100 COATED TABLETS**

**Important:** Read all product information before using. Do not use if foil inner seal is broken or missing.

**Drug Facts**

**Active ingredient (in each tablet)**  
Ibuprofen 200 mg (NSAID)\*.....Pain reliever/fever reducer  
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 ■ blister. 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

**REF: OTCM00020 (CONTINUED ON BACK OF LABEL)**  
www.medline.com Made in USA of Foreign and Domestic Materials. Manufactured for Medline Industries, LP, Three Lakes Drive, Northfield, IL 60093, USA 1-800-MEDLINE V1 RE22GAE R-00

LOT: (01)10193489141740  
EXP: \_\_\_\_\_  
Coating Free

PEEL HERE ↓

**Drug Facts (continued)**

**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! -800-222-1222, right away.

**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 at 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, polydioxane 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

<b>IBUPROFEN</b> ibuprofen tablet			
<b>Product Information</b>			
<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:53329-674
<b>Route of Administration</b>	ORAL		
<b>Active Ingredient/Active Moiety</b>			
	<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
	IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
<b>Inactive Ingredients</b>			
	<b>Ingredient Name</b>		<b>Strength</b>
	SILICON DIOXIDE (UNII: ETJ7Z6XBU4)		

<b>STARCH, CORN</b> (UNII: O8232NY3SJ)	
<b>FERRIC OXIDE RED</b> (UNII: 1K09F3G675)	
<b>POVIDONE K30</b> (UNII: U725QWY32X)	
<b>SODIUM STARCH GLYCOLATE TYPE A CORN</b> (UNII: AG9B65PV6B)	
<b>STEARIC ACID</b> (UNII: 4ELV7Z65AP)	
<b>TITANIUM DIOXIDE</b> (UNII: 15FIX9V2JP)	
<b>TALC</b> (UNII: 7SEV7J4R1U)	
<b>POLYVINYL ALCOHOL, UNSPECIFIED</b> (UNII: 532B59J990)	
<b>POLYETHYLENE GLYCOL, UNSPECIFIED</b> (UNII: 3WJQ0SDW1A)	

### Product Characteristics

<b>Color</b>	brown	<b>Score</b>	score with uneven pieces
<b>Shape</b>	ROUND	<b>Size</b>	10mm
<b>Flavor</b>		<b>Imprint Code</b>	G2
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:53329-674-30	1 in 1 CARTON	09/29/2017	
1		100 in 1 BOTTLE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	09/29/2017	

**Labeler** - Medline industries, LP (025460908)

**Registrant** - Medline Industries, LP (025460908)

Revised: 8/2023

Medline industries, LP