

IBUPROFEN- ibuprofen tablet
PuraCap Pharmaceutical LLC

Ibuprofen Tablets, USP 200 mg

Drug Facts

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

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 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, or kidney disease
- you have asthma
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

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
 - 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 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	<ul style="list-style-type: none">• 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	<ul style="list-style-type: none">• 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, corn starch, hypromellose, iron oxide red, lactose monohydrate, povidone k30, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

Questions or comments?

Call toll free: **1-855-215-8180**

PRINCIPAL DISPLAY PANEL

CVS Ibuprofen Tablets USP, 200 mg

NDC 51013-319-54



Compare to active ingredient in Advil®**

On-the-go Packettes

NDC 51013-319-54

Ibuprofen

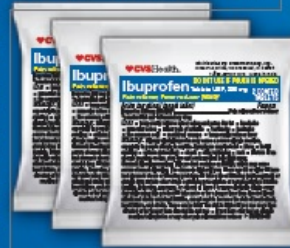
Tablets USP, 200 mg

Pain reliever;
Fever reducer (NSAID)*

Convenient on-the-go packettes



Tear Open
to Dispense



Actual Product Size
on Side Panel



Actual Size

Package Contains Fifteen Packettes

Actual Size

Distributed by: **CVS Pharmacy, Inc.**
One CVS Drive, Woonsocket, RI 02895
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CVS.com® 1-800-SHOP CVS

CVS29-00

Made in India
V-31204



#222654

FPO 80%
UPC# 050428589656

X XXXXXX XXXXXX X

Lot No.:

Exp. Date:

30 COATED TABLETS
15 PACKETTES (2 TABLETS PER PACKETTE)

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

Drug Facts

Active ingredient (in each tablet)

Ibuprofen 200 mg (NSAID)*Pain reliever/ fever reducer
*nonsteroidal anti-inflammatory drug

Purpose

Uses

- temporarily relieves minor aches and pains due to:
 - headache ■ muscular aches ■ minor pain of arthritis ■ toothache
 - backache ■ the common cold ■ menstrual cramps
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- shock ■ skin reddening ■ rash ■ blisters,

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- 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

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Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Ask a doctor before use if

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- the stomach bleeding warning applies to you
- you have a history of stomach problems, such as heartburn
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- under a doctor's care for any serious condition
- taking any other drug

Drug Facts (continued)

When using this product

- take with food or milk if stomach upset occurs
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

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 - feel faint ■ vomit blood
 - have bloody or black stools
 - have stomach pain that does not get better
- 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 right away. (1-800-222-1222)

Directions

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- the smallest effective dose should be used

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Other information

- Store between 20°-25°C (68°-77°F). (See USP Controlled Room Temperature)
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Inactive Ingredients colloidal silicon dioxide, corn starch, hypromellose, iron oxide red, lactose monohydrate, povidone K30, pregelatinized starch, sodium starch glycolate, stearic acid, titanium dioxide, triacetin

Questions or comments? Call toll free: 1-855-215-8180

****This product is not manufactured or distributed by Pfizer Consumer Healthcare, owner of the registered trademark Advil®.**

DO NOT USE IF PACKETTE IS TORN OR DAMAGED



Distributed by: **CVS Pharmacy, Inc.**
 One CVS Drive, Woonsocket, RI 02895
 1-800-SHOP CVS Made in India

Ibuprofen **DO NOT USE IF POUCH IS OPENED**
 Tablets USP, 200 mg **2 COATED TABLETS**
Pain reliever; Fever reducer (NSAID)*

<i>Active ingredient (in each tablet)</i>	<i>Purpose</i>
Ibuprofen 200 mg (NSAID)*	Pain reliever/fever reducer

*nonsteroidal anti-inflammatory drug

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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 ► CVSF28-00

■ 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.**
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) **Important: Read all product information before using. Keep the box for Important Information.**

CVSB28-00

IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:510 13-319
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
STARCH, CORN (UNII: O8232NY3SJ)	
POVIDONE K30 (UNII: U725QWY32X)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
HYPROMELLOSE 2208 (100 MPA.S) (UNII: B1QE5P712K)	
TRIACETIN (UNII: XHX3C3X673)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	

Product Characteristics

Color	RED	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	G;2
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51013-319-54	15 in 1 CARTON	11/09/2017	
1		2 in 1 POUCH; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079174	11/09/2017	

Labeler - PuraCap Pharmaceutical LLC (962106329)

Establishment

Name	Address	ID/FEI	Business Operations
Granules India Limited		918609236	MANUFACTURE(51013-319)

Revised: 11/2017

PuraCap Pharmaceutical LLC