

IBUPROFEN - ibuprofen tablet
Aurohealth LLC

Ibuprofen Tablets

Drug Facts

Active ingredient (in each caplet)

Ibuprofen USP 200 mg (NSAID)*

*nonsteroidal anti-inflammatory drug

Purposes

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 at 20 weeks or later in 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 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	<ul style="list-style-type: none"> • ask a doctor

Other information

- store between 20° to 25°C (68° to 77°F)
- **do not use if seal imprinted with SEALED for YOUR PROTECTION under the bottle cap is broken or missing.**
- see top panel for lot number and expiration date

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, FD&C red no. 40 aluminum lake, FD&C yellow no. 6 aluminum lake, hypromellose, microcrystalline cellulose, polyethylene glycol, stearic acid, titanium dioxide

Questions or comments?

Call **1-855-274-4122**

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road,
East Windsor, NJ 08520

Code No.: TS/DRUGS/22/2009

Made in India

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg (100 Tablets Bottle)

NDC 58602-801-21

Ibuprofen Tablets USP

200 mg

Pain Reliever/Fever Reducer (NSAID)

100 Coated Caplets*

****Capsule-Shaped Tablets***

AUROHEALTH

LOT:

EXP:

N
3

P1429937

NDC 58602-801-21

Ibuprofen Tablets USP
200 mg

Pain Reliever/Fever Reducer (NSAID)

100 Coated Caplets*

*Capsule-Shaped
Tablets

Do not use if seal imprinted with SEALED for
YOUR PROTECTION under the bottle cap is broken
or missing.

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

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Booklet

Page #2
(Back of Cover)

Page #3

[Back](#)

Front

Page #4

Cover
(Page #1)

Carton)

NDC 58602-801-21

#Compare to the active
ingredient of MOTRIN® IB

Ibuprofen Tablets USP

200 mg

Pain Reliever/Fever Reducer (NSAID)

100 Coated Caplets*

***Capsule-Shaped Tablets**

AUROHEALTH



IBUPROFEN

ibuprofen tablet

Product Information

Product Type

HUMAN OTC DRUG

Item Code (Source)

NDC:58602-801

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)	
STARCH, CORN (UNII: O8232NY3SJ)	
CROSCARMELOSE SODIUM (UNII: M28OL1HH48)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	

Product Characteristics			
Color	ORANGE (Light Orange to Orange)	Score	no score
Shape	CAPSULE (Biconvex)	Size	15mm
Flavor		Imprint Code	N;l
Contains			

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-801-07	1 in 1 CARTON	11/08/2017	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-801-12	1 in 1 CARTON	11/08/2017	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-801-14	1 in 1 CARTON	11/08/2017	
3		50 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-801-15	1 in 1 CARTON	11/08/2017	
4		60 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-801-19	1 in 1 CARTON	11/08/2017	
5		90 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-801-	1 in 1 CARTON	11/08/2017	

6	21	1 in 1 CARTON	11/08/2017	
6		100 in 1 BOTTLE; Type 0: Not a Combination Product		
7	NDC:58602-801-29	1 in 1 CARTON	11/08/2017	
7		150 in 1 BOTTLE; Type 0: Not a Combination Product		
8	NDC:58602-801-34	1 in 1 CARTON	11/08/2017	
8		200 in 1 BOTTLE; Type 0: Not a Combination Product		
9	NDC:58602-801-35	1 in 1 CARTON	11/08/2017	
9		225 in 1 BOTTLE; Type 0: Not a Combination Product		
10	NDC:58602-801-36	1 in 1 CARTON	11/08/2017	
10		250 in 1 BOTTLE; Type 0: Not a Combination Product		
11	NDC:58602-801-38	300 in 1 BOTTLE; Type 0: Not a Combination Product	11/08/2017	
12	NDC:58602-801-40	500 in 1 BOTTLE; Type 0: Not a Combination Product	11/08/2017	
13	NDC:58602-801-87	550 in 1 BOTTLE; Type 0: Not a Combination Product	11/08/2017	
14	NDC:58602-801-88	750 in 1 BOTTLE; Type 0: Not a Combination Product	11/08/2017	
15	NDC:58602-801-41	1000 in 1 BOTTLE; Type 0: Not a Combination Product	11/08/2017	
16	NDC:58602-801-59	1500 in 1 BOTTLE; Type 0: Not a Combination Product	11/08/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208865	11/08/2017	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-801) , MANUFACTURE(58602-801)