

IBUPROFEN - ibuprofen tablet
Aurohealth LLC

Ibuprofen Tablets

Drug Facts

Active ingredient (in each tablet)

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 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° 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 bottom panel for lot number and expiration date

Inactive ingredients

colloidal silicon dioxide, corn starch, croscarmellose sodium, hypromellose, microcrystalline cellulose, polyethylene glycol, red iron oxide, stearic acid, titanium dioxide and yellow iron oxide

Questions or comments?

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

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/16/2014

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

AUROHEALTH

NDC 58602-708-07

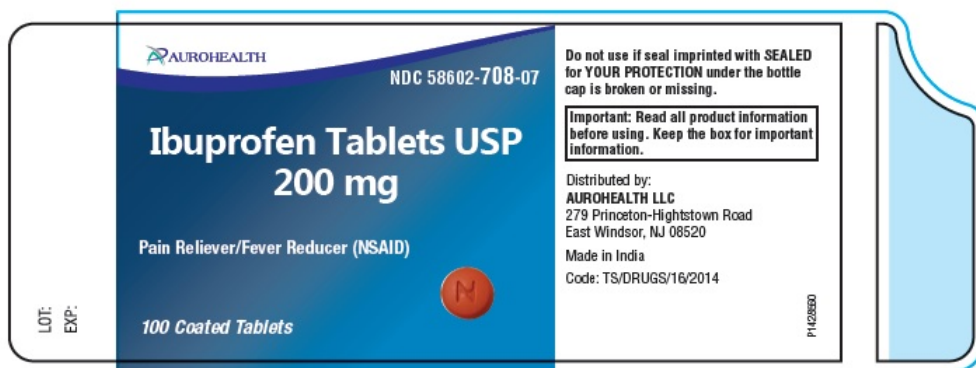
Ibuprofen Tablets USP

200 mg

Pain Reliever/Fever Reducer (NSAID)

100 Coated Tablets

Base Label



Booklet Placement

Booklet

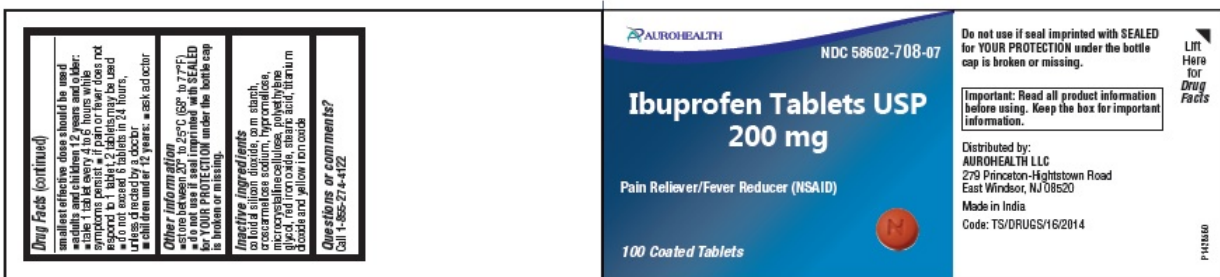
Use this for a 2-panel booklet

Page #2
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Page #3



Front



Page #4

Cover
(Page #1)

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

AUROHEALTH

NDC 58602-708-07

#Compare to the active ingredient of MOTRIN® IB

Ibuprofen Tablets USP
200 mg
Pain Reliever/Fever Reducer (NSAID)
100 Coated Tablets



IBUPROFEN

ibuprofen tablet

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-708
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)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	
POLYETHYLENE GLYCOL 400 (UNII: B697894SGQ)	
FERRIC OXIDE RED (UNII: 1K09F3G675)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
FERRIC OXIDE YELLOW (UNII: EX438O2MRT)	

Product Characteristics

Color	BROWN (Light Brown to Brown)	Score	no score
Shape	ROUND	Size	10mm
Flavor		Imprint Code	N;II
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-708-73	1 in 1 CARTON	03/22/2022	
1		24 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-708-09	1 in 1 CARTON	03/22/2022	
2		50 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-708-07	1 in 1 CARTON	03/22/2022	
3		100 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-708-53	1 in 1 CARTON	03/22/2022	
4		150 in 1 BOTTLE; Type 0: Not a Combination Product		
5	NDC:58602-708-83	1 in 1 CARTON	03/22/2022	
5		200 in 1 BOTTLE; Type 0: Not a Combination Product		
6	NDC:58602-708-49	300 in 1 BOTTLE; Type 0: Not a Combination Product	03/22/2022	
7	NDC:58602-708-01	1 in 1 CARTON	03/22/2022	
7		24 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
8	NDC:58602-708-05	1 in 1 CARTON	03/22/2022	
8		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

9	NDC:58602-708-08	1 in 1 CARTON	03/22/2022	
9		50 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
10	NDC:58602-708-15	1 in 1 CARTON	03/22/2022	
10		60 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
11	NDC:58602-708-06	1 in 1 CARTON	03/22/2022	
11		90 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
12	NDC:58602-708-02	1 in 1 CARTON	03/22/2022	
12		100 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
13	NDC:58602-708-03	1 in 1 CARTON	03/22/2022	
13		150 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
14	NDC:58602-708-04	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/22/2022	
15	NDC:58602-708-36	250 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/22/2022	
16	NDC:58602-708-75	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/22/2022	
17	NDC:58602-708-87	550 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/22/2022	
18	NDC:58602-708-52	700 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/22/2022	
19	NDC:58602-708-41	1000 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/22/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA208865	03/22/2022	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-708) , MANUFACTURE(58602-708)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-708) , MANUFACTURE(58602-708)