

IBUPROFEN - ibuprofen capsule
Aurohealth LLC

Ibuprofen Capsules

Drug Facts

Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen USP (NSAID)*
(present as the free acid and potassium salt)

*nonsteroidal anti-inflammatory drug

Purpose

Pain reliever/Fever reducer

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - toothache
 - backache
 - menstrual cramps
 - muscular aches
 - the common cold
 - minor pain of arthritis
- 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

- stomach bleeding warning applies to you
- you have problems or serious side effects from taking pain relievers or fever reducers
- 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

- under a doctor's care for any serious condition
- taking aspirin for heart attack or stroke, because ibuprofen may decrease this benefit of aspirin
- 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 (1-800-222-1222) right away.

Directions

- **do not take more than directed**
- **the smallest effective dose should be used**
- adults and children 12 years and over: take 1 capsule every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 capsule, 2 capsules may be used
- do not exceed 6 capsules in 24 hours, unless directed by a doctor
- children under 12 years: ask a doctor

Other information

- **each capsule contains:** potassium 20 mg
- read all warnings and directions before use. Keep carton.
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

black iron oxide, FD & C green no. 3, gelatin, hypromellose, polyethylene glycol, potassium hydroxide, propylene glycol, sorbitol sorbitan solution

Questions or comments?

call **1-855-274-4122**

Distributed by:

AUROHEALTH LLC

279 Princeton-Hightstown Road

East Windsor, NJ 08520

Made in India

Code No.: TS/DRUGS/22/2009

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg (40 Capsules Bottle)

NDC 58602-902-12

Ibuprofen Capsules

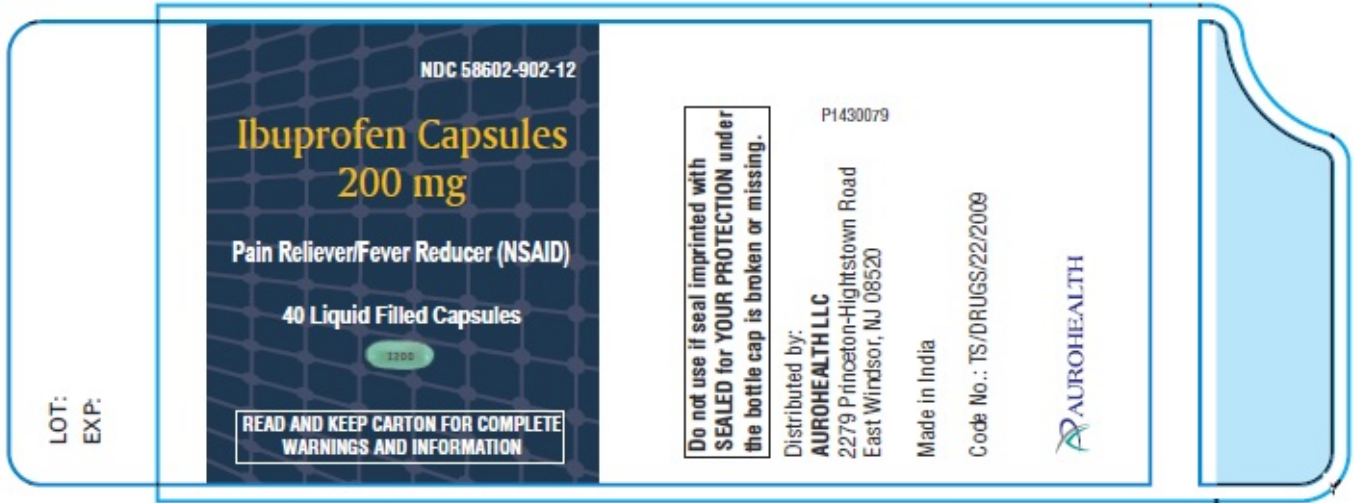
200 mg

Pain Reliever/Fever Reducer (NSAID)

40 Liquid Filled Capsules

**READ ANDA KEEP CARTON FOR COMPLETE
WARNING AND INFORMATION**

Base Label



Booklet Placement

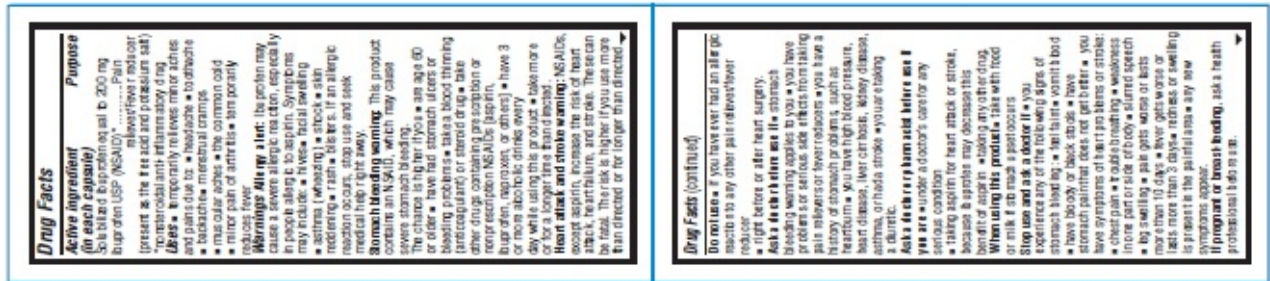
Booklet

Use this for a 2-panel booklet

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Page #3

Back



Front

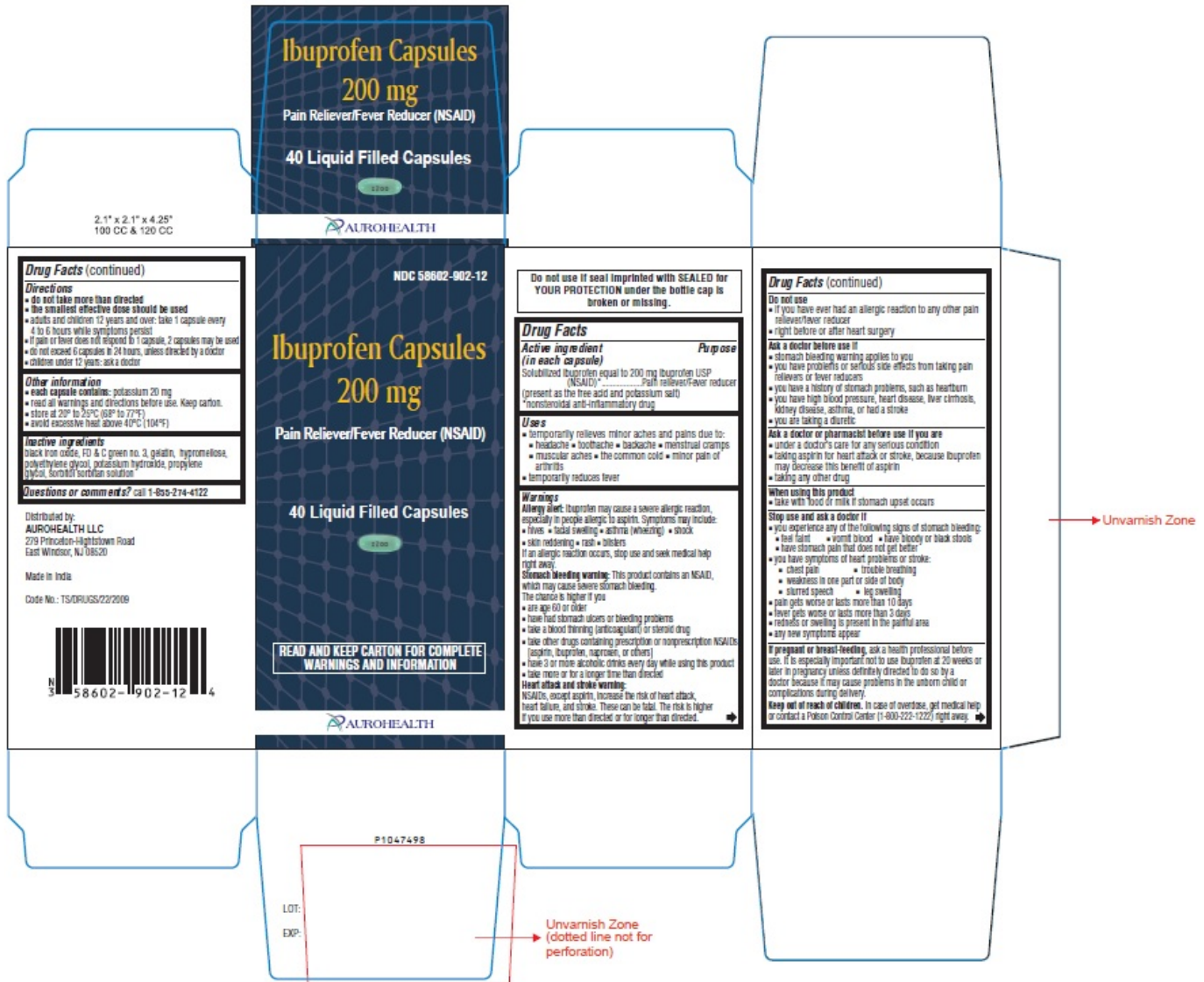


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Cover
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PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg (40 Capsules Container Carton)

NDC 58602-902-12
Ibuprofen Capsules
200 mg
Pain Reliever/Fever Reducer (NSAID)
40 Liquid Filled Capsules
READ AND KEEP CARTON FOR COMPLETE
WARNINGS AND INFORMATION
AUROHEALTH



IBUPROFEN
 ibuprofen capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-902
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
FERROSO FERRIC OXIDE (UNII: XM0M87F357)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
HYPROMELLOSE 2910 (6 MPA.S) (UNII: 0WZ8WG20P6)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
SORBITOL (UNII: 506T60A25R)	
1,4-SORBITAN (UNII: AV0YTZ4E6J)	
MANNITOL (UNII: 3OWL53L36A)	
WATER (UNII: 059QF0KO0R)	
ISOPROPYL ALCOHOL (UNII: ND2M416302)	

Product Characteristics

Color	GREEN	Score	no score
Shape	RECTANGLE (Oblong)	Size	19mm
Flavor		Imprint Code	I200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58602-902-73	1 in 1 CARTON	06/29/2018	
1		20 in 1 BOTTLE; Type 0: Not a Combination Product		
2	NDC:58602-902-12	1 in 1 CARTON	06/29/2018	
2		40 in 1 BOTTLE; Type 0: Not a Combination Product		
3	NDC:58602-902-18	1 in 1 CARTON	06/29/2018	
3		80 in 1 BOTTLE; Type 0: Not a Combination Product		
4	NDC:58602-902-30	160 in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2018	
5	NDC:58602-902-38	300 in 1 BOTTLE; Type 0: Not a Combination Product	06/29/2018	
6	NDC:58602-902-70	1 in 1 CARTON	03/31/2020	
6		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
7	NDC:58602-902-72	1 in 1 CARTON	03/31/2020	
7		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

8	NDC:58602-902-74	160 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2020	
9	NDC:58602-902-32	180 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2020	
10	NDC:58602-902-34	200 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2020	
11	NDC:58602-902-75	300 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207753	06/29/2018	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-902) , MANUFACTURE(58602-902)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		650381903	ANALYSIS(58602-902) , MANUFACTURE(58602-902)

Revised: 3/2022

Aurohealth LLC