

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
- store at 20° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

FD & C green no. 3, gelatin, polyethylene glycol, potassium hydroxide, purified water and 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: TS/DRUGS/16/2014

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 200 mg (300 Capsules Bottle)

HealthyLiving™

PAIN RELIEF

Ibuprofen Capsules 200 mg

Pain Reliever/Fever Reducer (NSAID)

**Compare
to the Active
Ingredient in
Advil®
LIQUI-GELS®†**

1200

300 Liquid Filled Capsules

Drug Facts (continued)

- muscular aches
- the common cold
- minor pain of arthritis
- temporarily reduces fever

Warnings

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- hives
- facial swelling
- asthma (wheezing)
- shock
- skin reddening
- rash
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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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PAIN RELIEF

Ibuprofen Capsules 200 mg

Pain Reliever/Fever Reducer (NSAID)

Compare to the Active Ingredient in Advil® LIQUI-GELS®

1200

300 Liquid Filled Capsules

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

Drug Facts

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Purpose Pain reliever/fever reducer (present as the free acid and potassium salt)
 *nonsteroidal anti-inflammatory drug

Uses

- temporarily relieves minor aches and pains due to:
 - headache
 - toothache
 - backache
 - menstrual cramps



B09JMLQMLS

Healthy Living Pain Relief Ibuprofen Capsules 200 mg 300 Count

P1430445

LM-4884

NVZ

PEEL BACK HERE

*Lot: XXXXXXXXXX
 EXP: MM/YYYY
 Prefix & Variables of Lot, EXP shall be printed online during packing.

Drug Facts (continued)

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
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- you have a history of stomach problems, such as heartburn
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- take with food or milk. If stomach upset occurs
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 - you experience any of the following signs of stomach bleeding:
 - feel faint
 - have bloody or black stools
 - have stomach pain that does not get better
 - you have symptoms of heart problems or stroke:
 - trouble breathing
 - weakness in one part or side of body
 - chest pain
 - arm pain
 - leg swelling
 - face, neck, or back pain
 - fever, get worse or lasts more than 3 days
 - redness or swelling is present in the painful area
 - any new symptoms appear.

Treatment 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 carefully directed to do so by a doctor because it may cause problems in the unborn child or complications during delivery.

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Other information

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

Inactive ingredients FD & C green no. 3, gelatin, polyethylene glycol, potassium hydroxide, purified water and sorbitol sorbitan solution.

Questions or comments? call 1-855-274-1122

This product is not manufactured or distributed by GLAXO-SMITHKLINE CONSUMER HEALTHCARE HOLDINGS US, LLC, distributor of Advil LIQUI-GELS®.

Distributed by:
 HUBBARD, LLC
 270 Precision-Highstown Road
 East Windsor, NJ 08820

Made in India
 Code: 150R08US/16/2014
 P 1430445 LM-4884

IBUPROFEN

ibuprofen capsule

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-852
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
FD&C GREEN NO. 3 (UNII: 3P3ONR601S)	
GELATIN, UNSPECIFIED (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL 600 (UNII: NL4J9F21N9)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITOL (UNII: 506T60A25R)	

1,4-SORBITAN (UNII: AV0Y TZ 4E6J)

MANNITOL (UNII: 3OWL53L36A)

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:58602-852-38	300 in 1 BOTTLE; Type 0: Not a Combination Product	07/18/2022	
2	NDC:58602-852-32	180 in 1 BOTTLE; Type 0: Not a Combination Product	07/18/2022	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA207753	07/18/2022	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-852) , MANUFACTURE(58602-852)

Revised: 7/2022

Aurohealth LLC