

SOUND BODY IBUPROFEN- ibuprofen 200 mg capsule, liquid filled

Allegiant Health

SoundBody Ibuprofen 200mg

Active ingredient (in each softgel)

Solubilized ibuprofen equal to 200mg ibuprofen (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
- the common cold
- muscular aches
- 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 a nonsteroidal anti-inflammatory drug (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, or kidney disease
- 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 older:

- take 1 softgel every 4 to 6 hours while symptoms persist
- if pain or fever does not respond to 1 softgel, 2 softgels may be used
- do not exceed 6 softgels in 24 hours unless directed by a doctor

Children under 12 years: ask a doctor

Other information

- **each softgel contains:** potassium 20mg
- store between 20-25 °C (68-77° F)
- Read all warnings and directions before use
- Do not use if seal under bottle cap is broken or missing.

Inactive ingredients

ammonium hydroxide, FD&C green #3 aluminum lake, gelatin, iron oxide black, medium chain triglycerides, polyethylene glycol, propylene glycol, potassium hydroxide, purified water, shellac, sorbitol sorbitan, sorbitan monooleate

Questions or comments?

Call 1-888-952-0050

Monday through Friday 9AM - 5PM EST.

Principal Display Panel

SOUNDBODY™

Compare to the active ingredient in Advil® Liqui-Gels®**

Ibuprofen

See New Warnings Information

Pain Reliever/Fever Reducer (NSAID)

40 Liquid Filled Capsules - **200 mg**

(softgel image) Actual Size

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

Distributed by: **Allegiant Health**

Deer Park, NY 11729

V#5003620 **PRODUCT OF INDIA** ITEM#FP0647

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Exp:
Lot:

Liqui-Gel is a registered trademark of
Cantel Pharma Solutions, Inc.



Drug Facts (continued)

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40 Liqui-Filled Capsules - 200mg

Ibuprofen
Pain Reliever / Fever Reducer (NSAID)



See How
Warnings
Information

Compare to the
active ingredients in
Advil® Liqui-Gels™

Drug Facts

Active ingredient
(in each softgel)

Purposes

nonsteroidal anti-inflammatory drug (present as the free acid and potassium salt)

Uses: temporarily relieves minor aches and pains due to: headache, toothache, backache, menstrual cramps, the common cold, muscular aches, 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 a nonsteroidal anti-inflammatory drug (NSAID), which may cause severe stomach bleeding. The chances are 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 everyday while using this product. **Heart attack and stroke warning:** NSAIDs,

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Ibuprofen

SOUND BODY IBUPROFEN

ibuprofen 200 mg capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69168-914
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
AMMONIA (UNII: 5138Q19F1X)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
GELATIN (UNII: 2G86QN327L)	
FERROSFERRIC OXIDE (UNII: XM0M87F357)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SHELLAC (UNII: 46N107B71O)	
SORBITOL MONOOLEATE (UNII: 658271J00C)	

Product Characteristics

Color	green (sea green)	Score	no score
Shape	CAPSULE	Size	15mm
Flavor		Imprint Code	133
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69168-914-40	1 in 1 CARTON	12/22/2014	
1		40 in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079205	12/22/2014	

