IBUPROFEN- ibuprofen capsule, liquid filled AAA Pharmaceutical, Inc.

RES - 1185A - 2019-0911

Drug Facts

Active ingredient (in each capsule)

Solubilized ibuprofen equal to

200 mg ibuprofen (NSAID)*

* 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 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

- side effects occur. You may report side effects to FDA at 1-800-FDA-1088.
- 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 during the last 3 months of 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 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
- store at 20-25°C (68-77°F)
- avoid excessive heat above 40°C (104°F)
- read all warnings and directions before use
- retain carton for complete product information and warnings

Inactive ingredients

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

PRINCIPAL DISPLAY PANEL

RESTORE U

NDC 57344-185-01

COMPARE TO THE ACTIVE INGREDIENT IN ADVIL® LIQUI-GELS®

Ibuprofen

Capsules, 200 mg

Pain Reliever/Fever Reducer

(NSAID)

actual size

20 SOFTGELS** (**liquid filled capsules)



Drug Facts

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■ take more or for a longer time than directed Heart attack and stroke warning: NSAIDs, except aspirn, 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. stomach bleeding warning applies to you
 you have problems or serious side effects from taking pain relievers or fever reducers reaction to any other pain reliever/fever reducer right before or after heart surgery Do not use ■ if you have ever had an allergic Ask a doctor before use if

you have a history of stomach problems, such as heartburn
 you have high blood pressure, heart disease, liver

unborn child or complications during delivery.

Keep out of reach of children. In case of pregnancy unless definitely directed to do so by a doctor because it may cause problems in the

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 buprofen may decrease this benefit of aspirin cirrhosis, kidney disease, asthma, or had a stroke
 you are taking a diuretic

Warnings
Allergy alert: Ibuprofen may cause a severe
allergic reaction, especially in people allergic to
aspirin. Symptoms may include:

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shock skin reddening arash shisters

temporarily reduces fever

minor pain of arthrits

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asthma (wheezing)rashblisters

edical help right away.

stomach bleeding. The chance is higher if you: are age 60 or older

Stop use and ask a doctor if

side effects occur. You may report side effects to

FDA at 1-800-FDA-1088.

take with food or milk if stomach upset occurs

When using this product

taking any other drug

have 3 or more alcoholic drinks every day while using this product

have stomach pain that does not get better you have symptoms of heart problems or stroke

Made in India

Lumberton, NJ 08048 1991 Main Street AAA Pharmaceutical, Inc. Distributed by:

Drug Facts (continued)

aheliac, sorbitan monocleate, sorbitol sorbitan glycol, potassium hydroxide, purified water, chain triglycerides, polyethylene glycol, propylene FD&C green #3, gelatin, iron oxide black, medium Inactive ingredients ammorium hydroxide,

have bloody or black stools

each capsule contains: potassium 20 mg
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Other information

RESTORE

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naproxen, or others)

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overdose, get medical help or contact a Poison Control Center right away (1-800-222-1222).

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children under 12 years: ask a doctor 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

Drug Facts (continued)

Drug Facts (continued)

■ 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 ■ weakness in one part or side of body
■ slurred speech ■ leg swelling

If pregnant or breast-feeding, ask a health professional before use. It is especially important not to use ibuprofen during the last 3 months of

NDC 57344-185-01

tCOMPARE TO THE ACTIVE INGREDIENT IN ADVIL® LIQUI-GELS®

Capsules, 200 mg Rellever/Fever Reducer
(NSAID)

20 SOFTGELS** (**liquid filled capsules)

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:57344-185
Route of Administration	ORAL		

EXPIRATION STAMPING FOR LOT AND INK AND COATING FREE

†This product is not manufactured or distributed by Pfizer Consur Healthcare, distributor of Advi?® Liqui-Gels® or Catalent Pharma Solutions, Inc., owner of the registered trademark Liqui-Gels®.

DO NOT USE IF IMPRINTED SEAL UNDER CAP IS BROKEN OR MISSING

F1185A01RES R0

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
IBUPRO FEN (UNII: WK2XYI10 QM) (IBUPRO FEN - UNII: WK2XYI10 QM)	IBUPROFEN	200 mg	

Inactive Ingredients		
Ingredient Name	Strength	
AMMO NIA (UNII: 5138 Q 19 F1X)		
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)		
GELATIN (UNII: 2G86QN327L)		
FERROUS OXIDE (UNII: G7036X8B5H)		
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)		
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)		
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)		
POTASSIUM HYDRO XIDE (UNII: WZH3C48 M4T)		
WATER (UNII: 059QF0KO0R)		
SHELLAC (UNII: 46N107B71O)		
SORBITAN MONOOLEATE (UNII: 06 XEA2 VD56)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristic	Product Characteristics			
Color	green	Score	no score	
Shape	CAPSULE	Size	19 mm	
Flavor		Imprint Code	133	
Contains				

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:57344-185- 01	1 in 1 CARTON	10 /0 1/20 18	
1		20 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:57344-185- 02	1 in 1 CARTON	10/01/2018	
2		40 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:57344-185- 03	1 in 1 CARTON	10/01/2018	
3		80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
4	NDC:57344-185- 04	160 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/01/2018	

Marketing Information				
ı	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

ANDA ANDA079205 10/01/2018

Labeler - AAA Pharmaceutical, Inc. (181192162)

Revised: 9/2019 AAA Pharmaceutical, Inc.