

IBUPROFEN- ibuprofen capsule, liquid filled
Healthy Accents (DZA Brands, LLC)

DRUG FACTS

Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg 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
 - 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

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

- the 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 or asthma
- 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
- the risk of heart attack or stroke may increase if you use more than directed or for longer than directed

Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
 - have bloody or black stools
 - vomit blood
 - have stomach pain that does not get better
 - 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 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° - 25°C (68°- 77°F)
- avoid excessive heat above 40°C (104°F). Protect from light.

Inactive ingredients

FD&C blue #1, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol

Questions or Comments ?

Call toll free **1-866-322-2439 Monday-Friday 9AM-5PM EST**

Principal Display Panel

Compare to Advil® Liqui-Gels® †
SOFTGELS**

** (LIQUID FILLED CAPSULES)

Ibuprofen Softgels

Solubilized Ibuprofen Capsules, 200 mg

- Pain reliever
- fever reducer (NSAID)

KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION

Do not use if tamper-evident seal under bottle cap imprinted with "SEALED for YOUR PROTECTION" is broken or missing

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

Manufactured by:

Banner Pharmacaps
4125 premier drive
High point NC 27265

Product Label

NO PRINT
NO VARNISH
NO COATING


NDC 55316-131-49

healthy accents®

ibuprofen softgels

solubilized ibuprofen capsules, 200 mg
pain reliever • fever reducer (NSAID)

40 softgels** (**liquid filled capsules)



NO PRINT
NO VARNISH
NO COATING

Ibuprofen softgels 200 mg

Drug Facts
Active ingredient (in each capsule) Purpose
Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID) 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
 - muscular aches
 - minor pain of arthritis
 - toothache
 - backache
 - 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)
- rash
- blisters

■ shock

■ skin reddening

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
- are on other 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

Do not use

- if you have ever had an allergic reaction to any other pain reliever/fever reducer
- right before or after heart surgery

Drug Facts (continued)

Ask a doctor before use if

- you are taking any other drug
- you have high blood pressure, heart disease, liver cirrhosis, kidney disease or asthma
- 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

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 - feel faint
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Drug Facts (continued)

Directions

- do not take more than directed
- the most 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 200 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). Protect from light.

Inactive ingredients: FD&C blue #1, gelatin, pharmaceutical ink, polyethylene glycol, potassium hydroxide, purified water, sorbitan, sorbitol

Questions or comments? Call toll free: 1-866-322-2439 Monday-Friday 9AM-5PM EST

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


KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

Manufactured by: Benet Pharmaceuticals Inc.
4125 Premier Drive
High Point, NC 27265
Rev# 03/12

FD-C
FD000922
Lot No.:
Exp. Date:

7 25439196268 1

Do not use if tamper-evident seal under bottle cap imprinted with SCALES® or 100% PROTECTION® is broken or missing.



Distributed by DAA Brands, LLC
Salem, NC 28147
For product questions or concerns
contact us at 1-866-322-2439.

IBUPROFEN			
ibuprofen capsule, liquid filled			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55316-131
Route of Administration	ORAL		
Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	

IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg
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Inactive Ingredients

Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0K00R)	
SORBITOL (UNII: 506T60A25R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

Color	BLUE	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	IB200
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55316-131-49	1 in 1 BOX		
1		40 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078682	12/11/2012	

Labeler - Healthy Accents (DZA Brands, LLC) (090322194)

Registrant - P and L Development of New York Corporation (800014821)

Revised: 3/2013

Healthy Accents (DZA Brands, LLC)