

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**

compare to active ingredient
of Advil® Liqui-Gels†

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

NDC 55316-131-49

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 pregnant or trying to get pregnant
- 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
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Stop use and ask a doctor if

- you experience any of the following signs of stomach bleeding:
 - feel faint
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- 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 6 months of pregnancy 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.

Drug Facts (continued)

Directions

- do not use 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®.

Manufactured by: Benet Pharmaceuticals Inc.
Rend 03/12 High Point, NC 27285

Do not use if tamper-evident seal under bottle cap imprinted with **SCALEX®** or **TOUR PHOTOGRAPHY** is broken or missing.

FD.C
F0000922
Lot No.:
Exp. Date:

7
25439196268
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Disturbed by DZA Brands, LLC
Salem, NC 28147
For product questions or concerns
contact us at 1-866-322-2439.



KEEP OUTER CARTON FOR COMPLETE WARNINGS AND PRODUCT INFORMATION.

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

| | | |
|------------------------------|-----------|--------|
| IBUPROFEN (IBUPROFEN) | IBUPROFEN | 200 mg |
|------------------------------|-----------|--------|

Inactive Ingredients

| Ingredient Name | Strength |
|----------------------|----------|
| FD&C BLUE NO. 1 | |
| GELATIN | |
| POLYETHYLENE GLYCOLS | |
| POTASSIUM HYDROXIDE | |
| WATER | |
| SORBITOL | |
| SORBITAN | |

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)