IBUPROFEN- ibuprofen capsule, liquid filled WinCo Foods, 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
 - o 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
 - o vomit blood
 - have stomach pain that does not get better
- pain gets worse or last more than 10 days
- fever gets worse or last 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.

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
 - o 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. 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 to report an adverse event call 800-824-1706 Monday-Friday 9am-4pm MST

Principal Display Panel

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

Ibuprofen

Ibuprofen Capsules 200 mg (NSAID)/

Pain Reliever-Fever Reducer

SOFTGELS**

**Liquid-Filled Capsules

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, distributor of Advil® Liqui-Gels®.

DISTRIBUTED BY: WINCO FOODS, LLC, BOISE, ID 83704

PRODUCT OF USA

Package Label

Exp. Date:

Lot No.:

Rev# 03/12

PLD-A7D FC002457 WF1411

Drug Facts (continued

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Shock skin reddening rash blisters

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DISTRIBUTED BY:

WINCO FOODS, LLC, BOISE, ID 83704

by PFIZER CONSUMER HEALTHCARE, distributor †This product is not manufactured or distributed PRODUCT OF U.S.A. of ADVIL® Liqui-Gels®

WARNINGS AND PRODUCT INFORMATION KEEP OUTER CARTON FOR COMPLETE

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using this product

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Relieves: Minor Aches & Pains, Fever

Softgels

**Liquid Filled Capsules

take other drugs containing prescription or nonprescription NSAIDs [aspirin, ibuprofen, naproxen, or others] have 3 or more alcoholic drinks every day while

WinCo FOODS Ibuprofen

IBUPROFEN CAPSULES 200 mg (NSAID)/

PAIN RELIEVER - FEVER REDUCER



WinCo Ibuprofen Softgels

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product TypeHUMAN OTC DRUGItem Code (Source)NDC:67091-141

Route of Administration ORAL

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

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Ingredient Name	Strength
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
GELATIN (UNII: 2G86QN327L)	
POLYETHYLENE GLYCOL, UNSPECIFIED (UNII: 3WJQ0SDW1A)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
WATER (UNII: 059QF0KO0R)	
SORBITAN (UNII: 6O92ICV9RU)	

Product Characteristics

SORBITOL (UNII: 506T60A25R)

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

Packaging

# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:67091-141- 80	1 in 1 BOX	12/31/2014	
1	80 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA078682	12/31/2014	

Labeler - WinCo Foods, LLC (056098817)

Revised: 12/2018 WinCo Foods, LLC