IBUPROFEN- ibuprofen capsule, liquid filled P & L Development, 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
 - toothache
 - backache
 - menstrual cramps
 - the common cold
 - muscular ache
 - 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 canbe 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

- 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 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° to 25°C (68° to 77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

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

Questions & Comments

Call 1-877-753-3935 Monday-Friday 9AM-5PM EST

Principal Display Panel

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

Ibuprofen Capsules, 200 mg

pain reliever/fever reducer (NSAID)

softgels**

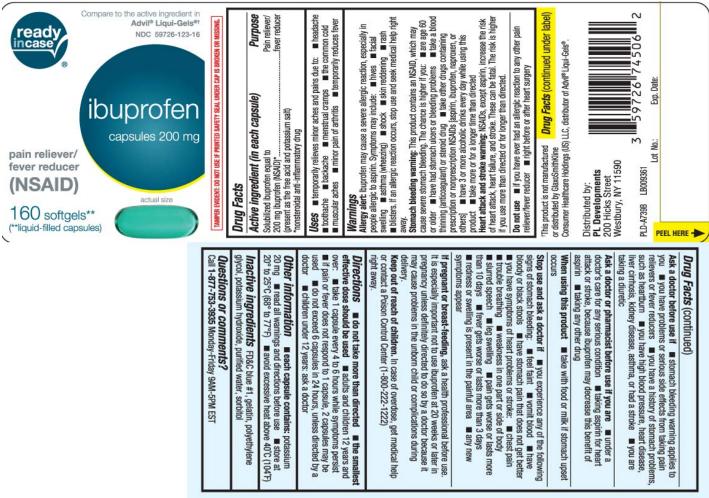
(**liquid-filled capsules)

†This product is not manufactured or distributed by GlaxoSmithKline Consumer Healthcare Holdings (US) LLC, distributor of Advil® Liqui-Gels®.

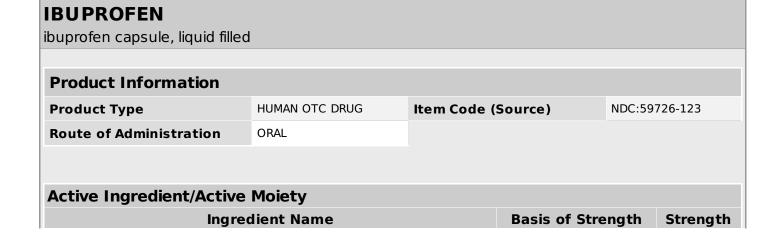
TAMPER EVIDENT: DO NOT USE IF PRINTED SAFETY SEAL UNDER CAP IS BROKEN OR MISSING.

Distributed by:
PL Developments
200 Hicks Street
Westbury, NY 11590

Product Label



READYinCASE Ibuprofen 200 mg Capsules



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

Inactive Ingredients		
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)		
SORBITOL (UNII: 506T60A25R)		

Product Characteristics			
Color	green (Blue)	Score	no score
Shape	CAPSULE	Size	19mm
Flavor		Imprint Code	A356
Contains			

ı	P	Packaging				
	#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
	1	NDC:59726- 123-16	160 in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	03/31/2023		

Marketing I	arketing Information		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202300	03/31/2023	

Labeler - P & L Development, LLC (800014821)

Revised: 4/2023 P & L Development, LLC