IBUPROFEN- ibuprofen capsule, liquid filled
J.P BUSINESS ENTERPRISE

IBUPROFEN softgels

Drug Facts

Active ingredient (in each capsule)

Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)[1] (present as the free acid and potassium salt)

---

[1] 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 a nonsteroidal anti-inflammatory drug (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 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
  - vomit blood
  - have bloody or black stools
  - 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
  - stomach pain or upset gets worse or lasts
  - 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**
- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- 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. Keep carton.
- store between 20°-25°C (68°-77°F)
- avoid excessive heat above 40°C (104°F)

Inactive ingredients

Ammonium hydroxide, FD&C green no. 3, Gelatin, Iron oxide black, Medium chain triglycerides, Polyethylene glycol, Propylene glycol, Potassium hydroxide, Purified water, Shellac, Sorbitan monooleate, Sorbitol sorbitan

Questions or comments?

1-888-333-9792

Distributed By: J.P Business Enterprise
Lake Grove, NY 11755

PRINCIPAL DISPLAY PANEL - 10 Softgel Bottle Carton

VALUMEDS

SEE NEW WARNINGS INFORMATION

Compare to the active ingredient
in **ADVIL® LIQUI-GELS®***

IBUPROFEN softgels

LIQUID FILLED IBUPROFEN CAPSULES, 200 mg

PAIN RELIEVER/FEVER REDUCER **(NSAID)**

10 SOFTGELS

IBUPROFEN

ibuprofen capsule, liquid filled

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:59105-002
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM)	IBUPROFEN	200 mg

Inactive Ingredients

Ingredient Name	Strength
AMMONIA (UNII: 5138Q19F1X)	
POLYETHYLENE GLYCOLS (UNII: 3WJQ0SDW1A)	
GELATIN (UNII: 2G86QN327L)	
FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S)	
FERROSOFERRIC OXIDE (UNII: XM0M87F357)	
WATER (UNII: 059QF0KO0R)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U)	
POTASSIUM HYDROXIDE (UNII: WZH3C48M4T)	
SHELLAC (UNII: 46N107B71O)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	

Product Characteristics

Color	GREEN	**Score**	no score
Shape	OVAL	**Size**	18mm
Flavor		**Imprint Code**	133
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:59105-002-10	1 in 1 CARTON		
1		10 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA079205	08/20/2013	

Labeler - J.P BUSINESS ENTERPRISE (078775890)

Revised: 8/2013 J.P BUSINESS ENTERPRISE