IBUPROFEN - ibuprofen capsule, liquid filled Walgreen Company

Active ingredient(s)

(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

Use(s)

- temporarily relieves minor aches and pain due to :
 - headache
 - toothache
 - backache
 - menstrual cramps
 - the common cold
 - muscular aches
 - minor pain of arthritis
- temporarily reduces fever

Warnings

Allergy alerts: 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

- 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

- 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 doctor if

- you experience any of following signs of stomach bleeding:
 - feel faint
 - vomit blood
 - have bloody or black stools
 - have stomach pain that dose 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 painful area
- any new symptoms appear

Pregnancy/Breastfeeding

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 a 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 ControlCenter right away.(1-800-222-1222)

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 dose 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

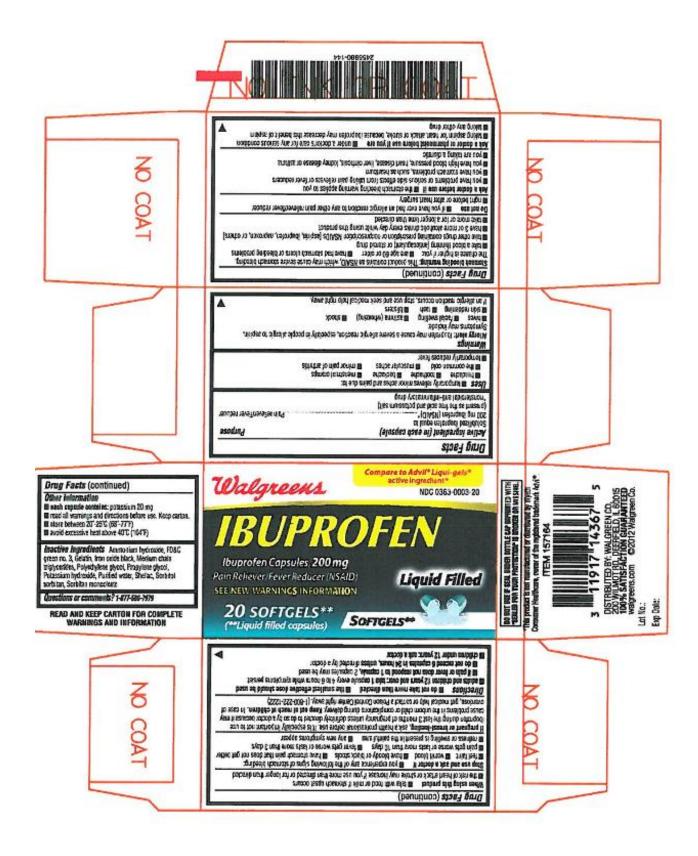
Other information

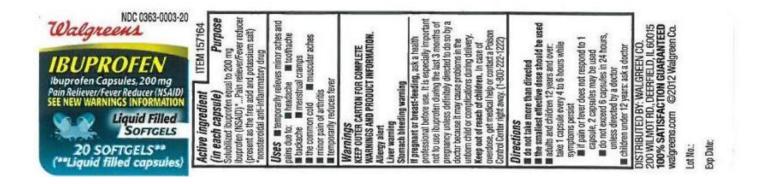
- each capsule contains: potassium 20 mg
- read all warnings and directions before use.
- store at 20-25 °C (68-77 °F)
- avoid excessive heat above 40 °C (104 °F)

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, Sorbitol, Sorbitan monooleate

Principal Display Panel





20ct_Label

Questions or Comments? 1-877-586-7979

IBUPROFEN

ibuprofen capsule, liquid filled

| Product Information | | | | | |
|-------------------------|----------------|--------------------|---------------|--|--|
| Product Type | HUMAN OTC DRUG | Item Code (Source) | NDC:0363-0003 | | |
| Route of Administration | ORAL | | | | |

| Active Ingredient/Active Moiety | | | | |
|--|-------------------|----------|--|--|
| Ingredient Name | Basis of Strength | Strength | | |
| IBUPROFEN (UNII: WK2XYI10QM) (IBUPROFEN - UNII:WK2XYI10QM) | IBUPROFEN | 200 mg | | |

| Ingredient Name | Strength |
|---|----------|
| AMMO NIA (UNII: 5138Q19F1X) | |
| FD&C GREEN NO. 3 (UNII: 3P3ONR6O1S) | |
| GELATIN (UNII: 2G86QN327L) | |
| SORBITOL (UNII: 506T60A25R) | |
| WATER (UNII: 059QF0KO0R) | |
| SHELLAC (UNII: 46 N10 7B710) | |
| SORBITAN MONOOLEATE (UNII: 06XEA2VD56) | |
| POLYETHYLENE GLYCOL (UNII: 3WJQ0SDW1A) | |
| PROPYLENE GLYCOL (UNII: 6 DC9 Q167V3) | |
| FERROSOFERRIC OXIDE (UNII: XM0 M8 7F357) | |
| MEDIUM-CHAIN TRIGLYCERIDES (UNII: C9H2L21V7U) | |
| PO TASSIUM HYDRO XIDE (UNII: WZH3C48 M4T) | |

| Product Characteristics | | | | | |
|-------------------------|---------|--------------|----------|--|--|
| Color | GREEN | Score | no score | | |
| Shape | CAPSULE | Size | 19 mm | | |
| Flavor | | Imprint Code | 133 | | |
| Contains | | | | | |

| P | Packaging | | | | | |
|---|------------------|---------------------|----------------------|--------------------|--|--|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date | | |
| 1 | NDC:0363-0003-20 | 1 in 1 CARTON | | | | |
| 1 | | 20 in 1 BOTTLE | | | | |
| 2 | NDC:0363-0003-40 | 1 in 1 CARTON | | | | |
| 2 | | 40 in 1 BOTTLE | | | | |
| 3 | NDC:0363-0003-80 | 1 in 1 CARTON | | | | |
| 3 | | 80 in 1 BOTTLE | | | | |
| 4 | NDC:0363-0003-16 | 1 in 1 CARTON | | | | |
| 4 | | 160 in 1 BOTTLE | | | | |

| Marketing Information | | | | |
|-----------------------|--|----------------------|--------------------|--|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date | |
| ANDA | ANDA079205 | 05/09/2011 | | |
| | | | | |

Labeler - Walgreen Company (008965063)

| Establishment | | | |
|--|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Aphena Pharma Solutions - Kentucky, LLC. | | 965013498 | repack |

| Establishment | | | |
|-------------------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Marksans Pharma Limited | | 925822975 | manufacture |

Revised: 5/2012 Walgreen Company