

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 21-472

FINAL PRINTED LABELING

Drug Facts

Active Ingredient (in each softgel)

Ibuprofen 200 mg

Purposes

Pain reliever/fever reducer

Uses

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

Warnings

Allergy alert: Ibuprofen may cause a severe allergic reaction which may include:

- hives
- facial swelling
- asthma (wheezing)
- shock

Alcohol warning: If you consume 3 or more alcoholic drinks every day, ask your doctor whether you should take ibuprofen or other pain relievers/fever reducers. Ibuprofen may cause stomach bleeding.

Do not use if you have ever had an allergic reaction to any other pain reliever/fever reducer

Ask a doctor before use if you have

- problems or serious side effects from taking pain relievers or fever reducers
- stomach pain

Ask a doctor or pharmacist before use if you are

- under a doctor's care for any serious condition
- taking any other product that contains ibuprofen, or any other pain reliever/fever reducer

When using this product take with food or milk if stomach upset occurs

Stop use and ask a doctor if

- an allergic reaction occurs. Seek medical help right away.
- 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.

Directions

- do not take more than directed
- adults and children 12 years and over
 - 1 softgel every 4 to 6 hours while symptoms persist
 - if pain or fever does not respond to 1 softgel, 2 softgels may be used
 - do not exceed 6 softgels in 24 hours, unless directed by a doctor
 - the smallest effective dose should be used
- children under 12 years: ask a doctor

Softgel (*give definition*)

Other information

- store at 20 - 25°C (68 - 77°F)
- avoid high humidity and excessive heat above 40°C (104°F)
- do not use if Tamper-Evident seal under bottle cap imprinted with "Sealed for Your Protection" is broken or missing

Inactive ingredients FD&C Blue #1, FD&C Yellow #5, gelatin, mannitol, polyethylene glycol, pharmaceutical ink, povidone, purified water, sorbitan, sorbitol, and vitamin E polyethylene glycol succinate

Questions or Comments?

call toll free 1-800-447-1140

[Please note: The font size, spacing, bolding, and formatting in this label are not necessarily compliant with § 201.66.]

