

ATTACHMENT 2

Ibuprofen Potassium and Phenylephrine HCl Soft Gelatin Capsules

Drug Facts

Active ingredients (in each capsule)

| | Purpose |
|---|-----------------------------|
| Solubilized ibuprofen equal to 200 mg ibuprofen (NSAID)* (present as the free acid and potassium salt) | Pain reliever/Fever reducer |
| Phenylephrine HCl 10 mg | Nasal decongestant |

Uses temporarily relieves these symptoms associated with the common cold, or flu:

- headache • fever • sinus pressure • nasal congestion • minor body aches and pains

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 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 an NSAID [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
- if you are now taking a prescription monoamine oxidase inhibitor (MAOI) (certain drugs for depression, psychiatric, or emotional conditions, or Parkinson's disease), or for 2 weeks after stopping the MAOI drug. If you do not know if your prescription drug contains an MAOI, ask a doctor or pharmacist before taking this product.

Ask a doctor before use if you have

- problems or serious side effects from taking pain relievers or fever reducers
- stomach problems that last or come back, such as heartburn, upset stomach, or stomach pain
- ulcers
- bleeding problems
- high blood pressure
- heart or kidney disease
- thyroid disease
- diabetes
- trouble urinating due to an enlarged prostate gland
- taken a diuretic
- reached age 60 or older

Ask a doctor or pharmacist before use if you are

- taking any other drug containing an NSAID (prescription or nonprescription)
- taking a blood thinning (anticoagulant) or steroid drug
- under a doctor's care for any serious condition
- taking any other product that contains phenylephrine, or any other nasal decongestant
- taking aspirin to prevent 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
- long term continuous use may increase the risk of heart attack or stroke

Stop use and ask a doctor if

- you feel faint, vomit blood, or have bloody or black stools. These are signs of stomach bleeding.
- pain gets worse or lasts more than 10 days
- fever gets worse or lasts more than 3 days
- nasal congestion lasts for more than 7 days
- symptoms continue or get worse
- stomach pain or upset gets worse or lasts
- redness or swelling is present in the painful area
- you get nervous, dizzy, or sleepless
- 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

- do not take longer than 10 days, unless directed by a doctor (see Warnings)
- adults and children 12 years of age and over:
 - take 1 capsule every 4 to 6 hours while symptoms persist. If symptoms do not respond to 1 capsule, 2 capsules may be used.
 - do not use more than 6 capsules in any 24-hour period unless directed by a doctor
- children under 12 years of age: consult a doctor

Other information

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

Inactive ingredients (To be determined)

Questions or Comments? (To be determined)

Distributed by (To be determined)