

ULTRAFEN PLUS

Tablets & Suspension

Composition

Ultrafen plus Suspension

Each 5 ml contains

Ibuprofen 100 mg

Pseudoephedrine Hcl 15 mg

Ultrafen plus Tablet

Each tablet contains

Ibuprofen 200 mg

Pseudoephedrine Hcl 30 mg

Action

Ibuprofen is a nonsteroidal anti-inflammatory compound used to relieve mild to moderate pain, fever, and inflammation. Ibuprofen is rapidly absorbed after oral administration and peak plasma concentrations occur about one to two hours after ingestion. Ibuprofen is 90 to 99% bound to plasma proteins and has a plasma half-life of about 2 hours. It is rapidly excreted in the urine mainly as metabolites and their conjugates. About 1% is excreted in urine as unchanged Ibuprofen and about 14% as conjugated Ibuprofen.

Pseudoephedrine produces vasoconstriction, acting on (alpha-adrenergic receptors in the mucosa of the respiratory tract. This action shrinks swollen nasal mucous membranes, thus reducing nasal congestion and thereby improving passage through the nasal airways. Sinus secretion is increased and the opening of obstructed eustachian tubes is facilitated.

The combination of ibuprofen and pseudoephedrine used to treat fever, body aches, and nasal congestion caused by the common cold, flu, or sinusitis.

Indications

Temporarily relieves these cold, sinus, and flu symptoms:

- Nasal and sinus congestion
- Minor body aches and pains
- Fever
- Stuffy nose
- Headache
- Sore throat

Contraindications

- If the patient ever had an allergic reaction to any other pain reliever/fever reducer and/or nasal decongestant.
- In a patient who is 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.

Warnings

Should be given with care to patients with asthma or bronchospasm, bleeding disorders, cardiovascular disease, a history of peptic ulceration, and in liver or renal failure. Patients with renal insufficiency require local synthesis of vasodilating prostaglandins to maintain renal perfusion, and therefore these patients are at greater risk of developing renal dysfunction due to NSAID-induced inhibition of renal prostaglandin synthesis.

Patients who are sensitive to aspirin or other NSAID's should generally not be given Ibuprofen. Ibuprofen should be discontinued in patients who experience blurred or diminished vision, or changes in color vision. Patients with collagen disease may be at increased risk of developing aseptic meningitis.

Caution needed when given to patients with diabetes mellitus or closed angle glaucoma. Use with care, or avoid usage in patients undergoing anesthesia with cyclopropane, halothane or other halogenated anesthetics, as they may induce ventricular fibrillation. Interactions of sympathomimetic agents with alpha- and beta blocking medicines may be complex.

Adverse Reactions

Nausea, vomiting, epigastric pain, heartburn, diarrhea, constipation, peptic ulcer, black-tarry stools. Nervousness, tinnitus, headache, dizziness, insomnia, excitability, drowsiness, restlessness. Tachycardia, palpitation, pressor activity, cardiac arrhythmias, cardiovascular collapse. Decreased blood counts. Rash, allergic reactions, edema

Precautions

Allergy alert

Ibuprofen may cause a severe allergic reaction that may include:

- Hives
- Facial swelling
- Asthma (wheezing)
- Shock

Sore throat warning

Severe or persistent sore throat or sore throat accompanied by high fever, headache, nausea, and vomiting may be serious. Consult a doctor promptly. Do not use more than 2 days or administer to children less than 3 years of age unless directed by a doctor.

Pregnancy

Category B (1st and 2nd trimesters)

Animal reproduction studies have failed to demonstrate a risk to the fetus and there are no adequate and well-controlled studies in pregnant women.

Category D (If used in 3rd trimester)

There is positive evidence of human fetal risk based on adverse reaction data from investigational or marketing experience or studies in humans, but potential benefits may warrant use of the drug in pregnant women despite potential risks.

Nursing Mothers

Small amounts of ibuprofen and pseudoephedrine may pass into breast milk, but this is not expected to be harmful to a nursing infant.

Drug Interactions

Pseudoephedrine

Sympathomimetics

Concomitant administration of pseudoephedrine with other sympathomimetic agents may cause a rise in blood pressure, as well as produce additive effects and increased toxicity.

Monoamine oxidase inhibitors

May produce a hypertensive crisis. Serious toxicity may result if pseudoephedrine is used with monoamine oxidase inhibitors.

Anti-hypertensive agents

Coadministered pseudoephedrine may alter the hypotensive effect of guanethidine and could produce a loss of blood pressure control, hypertensive episodes, and/or cardiac arrhythmias.

Coadministered pseudoephedrine may alter the antihypertensive effect of methyldopa and reserpine and could produce a loss of blood pressure control and an increase in the risk of hypertensive episodes

Beta- adrenergic blocking drugs such as propranolol may increase the toxicity to pseudoephedrine. The drug interaction between beta-1 selective blocking agents and pseudoephedrine is less likely but theoretically possible.

Antidepressants

Pseudoephedrine may interact with antidepressant medication.

Ibuprofen

Coumarin-type Anticoagulants

Because bleeding has been reported when ibuprofen and other NSAID's have been administered to patients on coumarin-type anticoagulants, physicians should exercise caution when administering Ibuprofen to patients on anticoagulants.

Acetylsalicylic Acid (Aspirin)

Aspirin administered with NSAID's causes a decrease in blood levels and activity of non-salicylate drugs. Since concomitant use offers no therapeutic advantage, such combinations should be avoided.

Methotrexate

Ibuprofen, as well as other NSAID's, may enhance the toxicity of Methotrexate. Caution should be used if Ibuprofen is administered concomitantly with Methotrexate.

Furosemide

Ibuprofen can reduce the natriuretic effect of furosemide and thiazides in some patients. During concomitant therapy with Ibuprofen, patients should be observed closely for signs of renal failure, as well as to assure diuretic efficacy.

Lithium

Ibuprofen produced an elevation of plasma lithium levels and a reduction in renal lithium clearance. Therefore, when Ibuprofen and lithium are administered concurrently, patients should be observed carefully for signs of lithium toxicity.

Dosage and Administration

Not recommended for children under the age of two years.

Ultrafen Plus Suspension

Children aged 2 –5 years: One teaspoonful (5 ml).

Children aged 6 –11 years: Two teaspoonfuls (10 ml).

Doses may be repeated every 4 –6 hours as needed. Do not exceed 4 doses in 24 hours.

Ultrafen Plus Tablet

Adults (and children over 12 years): One tablet every 4 to 6 hours. If symptoms do not respond to one tablet, a second may be taken. Do not exceed six tablets in 24 hours.

Ultrafen Plus should be taken with food or milk or after meals.

Do not use continuously for colds for more than 7 days or for fever for more than 3 days unless directed by your doctor. If the cold or fever persists or worsens, or if new symptoms occur, consult your doctor.

Over dosage

Manifestation

The most frequently reported symptoms of Ibuprofen overdose include abdominal pain, nausea, vomiting, lethargy and drowsiness. Other central nervous system symptoms include headache, tinnitus, CNS depression, and seizures. Metabolic acidosis, coma, acute renal failure, and apnea (primarily in very young children) may rarely occur. Cardiovascular toxicity, including hypotension, bradycardia, tachycardia, and atrial fibrillation has been reported.

Symptoms from pseudoephedrine overdose consist most often of mild anxiety, tachycardia, and/or mild hypertension.

Treatment

The treatment of acute ibuprofen overdose is primarily supportive. Management of hypotension, acidosis and gastrointestinal bleeding may be necessary. In cases of acute overdose, the stomach should be emptied through ipecac-induced emesis or lavage. Emesis is most effective if initiated within 30 minutes of ingestion. Orally administered activated charcoal may help in reducing the absorption and re-absorption of ibuprofen.

In children, the estimated amount of ibuprofen ingested per body weight may be helpful to predict the potential for development of toxicity although each case must be evaluated. Ingestion of less than 100 mg/kg is unlikely to produce toxicity.

Children ingesting 100 to 200 mg /kg may be managed with induced emesis and a minimal observation time of four hours. Children ingesting 200 to 400 mg/ kg of ibuprofen should have immediate gastric emptying and at least four hours observation in a health care facility.

Children ingesting greater than 400 mg/kg require immediate medical referral, careful observation, and appropriate supportive therapy. Ipecac-induced emesis is not recommended in overdoses greater than 400 mg/kg because of the risk of convulsions and the potential for aspiration of gastric contents.

In adult patients, the history of the dose reportedly ingested does not appear to be predictive of toxicity. The need for referral and follow-up must be judged by the circumstances at the time of the overdose ingestion. Symptomatic adults should be admitted to a health care facility for observation. Symptoms from pseudoephedrine

Presentation

Ultrafen plus Suspension

Bottle of 100 ml

Ultrafen plus Tablet

Box of 20 tablets