

EXTRAFEN

Suspension

Composition

Each 5 ml contains:

Ibuprofen	100 mg
Paracetamol	125 mg

Action

Paracetamol has analgesic and antipyretic effects. Ibuprofen has analgesic, antipyretic, and anti-inflammatory activities. Ibuprofen inhibits platelet aggregation.

Pharmacokinetics

Paracetamol: Absorption following oral administration is well and almost complete.

Paracetamol is metabolised in the liver primarily by conjugation. Paracetamol has half-life of 1 to 4 hours, time to peak concentration of 0.5 to 2 hours, time to peak effect of 1 to 3 hours and the duration of action of 3 to 4 hours. Paracetamol is renally excreted primarily as metabolites and 3% of a dose may be excreted unchanged.

Ibuprofen: Well absorbed after oral administration. Onset of action for pain relief is 30 minutes and the time for peak effect for fever is 2 to 4 hours. The half-life of ibuprofen is about 2 hours and the duration of action for fever is 6 to 8 hours or more and is 4 to 6 hours for pain. More than 90% of an ingested dose is excreted in the urine as metabolites or their conjugates. Protein binding of ibuprofen is more than 95%.

Indications

Extrafen is indicated for the reduction of fever in patients' ages 1 year and older and discomfort due to cold and "flu", and of simple pain and discomfort due to teething, immunizations, and tonsillectomy.

Contraindications

Do not give this medication if the child has any of the following:

- History of gastrointestinal bleeding
- Kidney or liver disease
- Allergic reactions to aspirin or related drugs
- Anemia
- Blood-clotting defect

Adverse Reactions

Stomach upset or discomfort is the most common side effect. Taking Extrafen with food may help.

Precautions

General

Blurred and/or diminished vision, scotomata, and/or changes in color vision have been reported. If a patient develops such complaints while receiving Extrafen the drug should be discontinued and the patient should have an ophthalmologic examination that includes central visual fields and color vision testing.

Ibuprofen, like other nonsteroidal anti-inflammatory agents, can inhibit platelet aggregation, but the effect is quantitatively less and of shorter duration than that seen with aspirin. Ibuprofen has been shown to prolong bleeding time (but within the normal range), in normal subjects. Because this prolonged bleeding effect may be exaggerated in patients with underlying hemostatic defects, Extrafen should be used with caution in persons with intrinsic coagulation defects and those on anticoagulant therapy.

The antipyretic and anti-inflammatory activity of ibuprofen may reduce fever and inflammation, thus diminishing their utility as diagnostic signs in detecting complications of presumed noninfectious, non-inflammatory painful conditions

Pregnancy

Safety and efficacy in pregnancy and lactation have not been established.

Non-steroidal anti-inflammatories are not recommended in the second and third trimesters because of possible adverse effects on the fetus, such as premature closure of the ductus arteriosus.

Administration of Extrafen is not recommended during pregnancy.

Nursing Mothers

Because of the limited nature of the studies and the possible adverse effects of prostaglandin-inhibiting drugs on neonates, Extrafen is not recommended for use by nursing mothers.

Infants

Safety and efficacy of Extrafen in children below the age of 1 year has not been established.

Liver Effects

As with other nonsteroidal anti-inflammatory drugs, borderline elevations of one or more liver function tests may occur in up to 15% of patients. These abnormalities may progress, may remain essentially unchanged, or may be transient with continued therapy. The SGPT (ALT) test is probably the most sensitive indicator of liver dysfunction. A patient with symptoms and/or signs suggesting liver dysfunction, or in whom an abnormal liver test has occurred, should be evaluated for evidence of the development of more severe hepatic reactions while on therapy with Ibuprofen. Severe hepatic reactions, including jaundice and cases of fatal hepatitis have been reported with ibuprofen as with other nonsteroidal anti inflammatory drugs. Although such reactions are rare, if abnormal liver tests persist or worsen, if clinical signs and symptoms consistent with liver disease develop, or if systemic manifestations occur (e.g., eosinophilia, rash, etc) Extrafen should be discontinued.

Aseptic Meningitis

Aseptic meningitis with fever and Coma has been observed on rare occasions in-patients on ibuprofen therapy. Although it is probably more likely to occur in patients with systemic lupus erythematosus and related connective tissue diseases, it has been reported in patients who do not have an underlying chronic disease. If signs or symptoms of meningitis develop in a patient, the possibility of its being related to ibuprofen should be considered.

Renal Effects

Since primarily the kidneys, patients with, eliminate ibuprofen, significantly, impaired renal function should be closely monitored, and a reduction in dosage should be anticipated to avoid drug accumulation.

Drug Interactions

Blood thinners (anticoagulants)

Corticosteroids (such as Prednisone)

Aspirin

Furosemide

Lithium

Dosage and Administration

DO NOT EXCEED THE RECOMMENDED DOSE.

SHAKE BOTTLE BEFORE USE.

Adults and children over twelve years:

One to two medicine measuresful (5 - 10 ml) four hourly if necessary and not more than six medicine measuresful in twenty-four hours.

Children six to twelve years old:

One to two medicine measuresful (5 - 10 ml) three to four times daily.

Children two to five years old:

Half to one medicine measuresful (2,5 - 5 ml) three to four times daily.

Extrafen should be taken with or after food.

If taking Extrafen for pain and the pain persists for longer than 7 days, or if taking Extrafen for fever and the fever persists for longer than 3 days or if the condition deteriorates or new symptoms develop, a re-evaluation of the condition is required by the doctor. Not recommended for children under 1 year of age or for children weighing less than 7 kg.

Over Dosage

There is no specific antidote to ibuprofen. The following signs and symptoms have been reported: headache, vomiting, drowsiness, loss of consciousness and hypotension. Symptomatic treatment is recommended, directed at maintaining normal blood pressure and correcting any electrolyte imbalance, particularly potassium. Emesis may need to be considered but only after careful assessment of the patient's condition, in particular the level of consciousness. As the drug is acidic and excreted in the urine, theoretically it would be advantageous to administer alkali and induce diuresis. Patients who have taken an overdose of paracetamol may appear well for the first three days, and then succumb to liver damage.

The hepatic changes produced by over dosage of paracetamol result from the accumulation of a highly active intermediate metabolite in the hepatocytes. N-acetylcysteine intravenously or 1-methionine orally protects the liver if administered within 10-12 hours of ingesting an overdose.

Presentation

Bottle of 100 ml suspension.