Emifen®

Antirheumatic, Anti-inflammatory, Analgesic

Composition:
Emifen Tablets 400 mg: Each film coated tablet contains 400 mg Ibuprofen BP.
Emifen Tablets 600 mg: Each film coated tablet contains 600 mg Ibuprofen BP.
Emifen Suspension: Each 5 ml contains 100 mg Ibuprofen BP.

Properties:
Emifen (ibuprofen) is a non-steroidal anti-inflammatory agent. It possesses anti-inflammatory, analgesic and antipyretic properties and it is effective in the relief of inflammatory and painful conditions. Ibuprofen acts by inhibiting prostaglandin biosynthesis, by decreasing the activity of the enzyme, cyclo-oxygenase, and results in decreased formation of prostaglandin precursors, which plays a major role in causing inflammation, pain and fever.

Pharmacokinetics:
Emifen is administered orally and is approximately 80% absorbed from the gastrointestinal tract. Emifen suspension is absorbed at about twice the rate of Emifen tablet. Although absorption is slower if the drug is taken with food, the extent of absorption is not affected. Peak plasma concentrations are reached within 1-2 hours after a dose. In children, the antipyretic effect begins within 1 hour and peaks within 2-4 hours. Ibuprofen is highly protein-bound (about 90-99%) and undergoes biotransformation in the liver. The plasma half-life is between 2 and 4 hours. Ibuprofen is excreted in the urine, 50-60% as metabolites and approximately 10% as unchanged drug.

Indications:
Emifen is indicated in the treatment of:
- Rheumatoid arthritis, osteoarthritis and allied conditions, non-articular rheumatism and soft tissue injuries.
- Juvenile arthritis.
- Painful inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea.
- Post-traumatic and postoperative pain, inflammation and swelling e.g. following dental or orthopaedic surgery.
- Acute attack of gout.
- Migraine headache.
- Fever and pain in children.

Dosage and Administration:
Adults:
The recommended initial daily dosage is 1200 mg- 1800 mg in 3-4 divided doses preferably after food.
Some patients can be maintained on 600 mg- 1200 mg daily in divided doses.
The total daily dose of Emifen should not exceed 2400 mg.
Children:
The recommended dose in juvenile rheumatoid arthritis for children over 7 kg body weight is 30-40 mg/Kg daily in 3-4 divided doses.
For pain and fever in children, the recommended dose for children over 7 kg body weight is 20-30 mg/kg daily in divided doses or
1-2 years: 2.5 ml Emifen supension (50 mg) 3-4 times daily,
3-7 years: 5 ml Emifen suspension (100 mg) 3-4 times daily,
8-12 years: 10 ml Emifen suspension (200 mg) 3-4 times daily.
Emifen is not recommended for children weighing less than 7 kg.
Elderly:
For elderly patients, no dosage adjustment is required, unless renal or hepatic function is impaired, in which case the dosage of Emifen should be individually adjusted.

Contraindications:
In patients hypersensitive to ibuprofen or it's components
Emifen like other non-steroidal anti-inflammatory drugs should not be given to patients with active peptic ulcer and to patients in whom attacks of asthma, angioedema, urticaria or acute rhinitis are precipitated by aspirin or any other NSAIDs.

Warnings
Cardiovascular risk:
NSAIDs may cause an increased risk of serious cardiovascular thrombotic events, myocardial infraction, and stroke, which can be fatal. This risk may increase with duration of use. Patients with cardiovascular disease or risk factors for cardiovascular disease may be at greater risk.
Gastrointestinal risk:
NSAIDs cause an increased risk of serious gastrointestinal adverse events including bleeding ulceration, and perforation of the stomach or intestines, which can be fatal. These events can occur at any time during use and without warning symptoms.
Elderly patients are at greater risk for serious gastrointestinal events.

Insert code: LFT 0001 (B) March 2007

Precautions:
Emifen should be used with caution in the elderly. In patients with hypertension, congestive heart failure, renal, or hepatic impairment caution is required since the use of NSAIDs may result in deterioration of renal function. The dose should be kept as low as possible and renal function should be monitored in these patients. Emifen should also be used with caution in patients with history of gastrointestinal disease (bleeding or ulcers) or those receiving anticoagulants.
Emifen suspension contains sunset yellow (FD&C yellow No. 6)

Use in Pregnancy and Lactation:
Emifen should not be used during pregnancy particularly the last three months owing to the possibility of uterine inertia and/or premature closure of the ductus arteriosus. Ibuprofen is excreted in breast milk in very low concentrations and is unlikely to affect the breast-fed infant adversely.

Side effects:
-The most commonly observed Side effects are Nausea, vomiting, diarrhoea, dyspepsia, haematemesis, ulcerative stomatitis and gastrointestinal haemorrhage.
-Less frequently, gastritis, duodenal ulcer, gastric ulcer and gastrointestinal perforation.
-Hypersensitivity reactions and anaphylaxis, asthma, aggravated asthma, bronchospasm , dyspnoea and assorted skin disorders have been reported.
- Other side effects have been reported include Photosensitivity, visual disturbance, hepatitis, jaundice, optic neuritis, depression, confusion, agranulocytosis, a plastic anemia, hemolytic anemia.Oedema, Nephrotoxicity, Abnormal liver function, dizziness, nervousness, drowsiness, insomnia, vertigo, tinnitus, thrombocytopenia and neutropenia .

Drug interactions:
In therapeutic doses, no evidence of clinically significant interactions with other commonly used drugs has been observed. However, as with other NSAIDs, it may increase digoxin, methotrexate, lithium and cyclosporin serum concentrations.
Ibuprofen may enhance the effect of oral anticoagulants. Also caution should be exercised in patients receiving antihypertensives and diuretics as reduced effect of these drugs may occur. NSAIDs should not be used for 8-12 days after mifepristone administration as NSAIDs can reduce the effects of mifepristone. Corticisteroids may increase risk of gastrointestinal bleeding. Patients taking NSAIDs and quinolone antibiotics may have an increased risk of developing convulsions associated with quinolone antibiotics. Concomitant administration of other NSAIDs may increase gastrointestinal adverse effects.

Overdosage:
- Symptoms include nausea, vomiting, dizziness and rarely, loss of consciousness.
- Large overdoses are generally well tolerated when no other drugs are involved.
-Gastric lavage may be of value for a considerable time after ingestion. And if necessary, correct serum electrolytes and implement appropriate supportive measures.
-There is no specific antidote to ibuprofen.

Presentation:
Emifen 400 mg film coated tablets in packs of 20 FC Tablets.
Emifen 600 mg film coated tablets in packs of 20 FC Tablets.
Emifen Suspension 100 mg/ 5 ml in bottles of 100 ml

Store below 25°C in a dry place. Protect from light.

Shake the suspension well before use.

THIS IS A MEDICAMENT

- A Medicament is a product, which affects your health, and its consumption, contrary to instruction, is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not, by yourself, interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.

Keep medicaments out of the reach of children

Council of Arab Health Ministers
Union of Arab Pharmacist

globalpharma L.L.C.
Dubai-UAE