Emifenac ®

Analgesic, Anti-inflammatory

Composition:
Emifenac 50 DT: Each Emifenac 50 DT dispersible tablet contains diclofenac free acid 46.5 mg equivalent to diclofenac sodium 50 mg.
Diclofenac free acid
{2-[(2,6-dichlorophenyl)-amino]-phenyl}-acetic acid (=diclofenac free acid)
Emifenac 50 DT Dispersible Tablets, specifically to disintegrate quickly in water, yielding a tasteless suspension of diclofenac free acid. The suspension is to be taken orally.

Emifenac 100 SRT: Each Emifenac 100 SRT sustained release tablet contains diclofenac sodium 100 mg.

Properties:
Emifenac (diclofenac) is a non-steroidal anti-inflammatory compound with pronounced analgesic, anti-inflammatory and antipyretic properties. Diclofenac acts by inhibiting prostaglandin biosynthesis by decreasing the activity of the enzyme, cyclo-oxygenase and results in decreased formation of prostaglandin precursors, which play a major role in causing inflammation pain and fever.
Emifenac 50 DT has a rapid onset of action, which makes them particularly suitable for the treatment of acute painful and inflammatory conditions, and for those patients who have difficulty in swallowing conventional tablets.
Emifenac 100 SRT in a single dose simplifies long-term treatment in particular and helps to avoid the possibility of dosage errors.

Pharmacokinetics:
Emifenac 50 DT: Absorption of diclofenac from Emifenac 50 DT dispersible tablets sets in immediately after administration. The time to achieve maximum plasma concentration is attained on average 1 hour after ingestion of one Emifenac 50 DT dose on an empty stomach.
Emifenac 100 SRT: the sustained release tablets are completely absorbed from GIT as diclofenac is released slowly; peak plasma concentration is lower than those attained after administration of conventional dosage forms.
The bioavailability of diclofenac from Emifenac is 82% of the bioavailability of Emifenac enteric-coated tablets. Administration of diclofenac together with or immediately after a meal does not delay the onset of absorption but reduces the amount absorbed by an average of about 16% and the maximum concentrations by about 50%.
Diclofenac appears to be widely distributed in the body, with significant amounts in synovial fluid (present in the joints) the concentrations attained in the synovial fluid are higher than those in plasma and remain higher for up to 12 hours.
Diclofenac is metabolized in the liver and the metabolites are excreted in the urine and the bile. The elimination half-life is about 1-2 hours following oral administration.

Indications:
Emifenac is indicated in the following conditions:
- Post-operative pain, inflammation and swelling e.g. following dental or orthopedic surgery.
- Painful post-traumatic inflammatory states, e.g. due to sprains.
- Non-articular rheumatism.
- Painful symptoms of the vertebral column.
- Painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea.
- Acute attacks of gout.
- As an adjuvant in severe painful inflammatory infections of the ear, nose or throat, e.g. pharyngitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication.

Dosage and Administration:
Emifenac 50 DT: Emifenac 50 DT dispersible tablets should preferably be taken before meals.
Emifenac 50 DT dispersible tablets are dropped into a glass of water and stirred to aid dispersion before swallowing. Since a portion of the active substance (diclofenac) may remain in the glass after swallowing, it is advisable to rinse the glass with a small of water and to swallow again.
Adults: The recommended initial dosage is 2-3 Emifenac 50 DT dispersible tablets. In milder cases as well as for children over 14 years of age, 2 Emifenac 50 DT dispersible tablets daily are usually sufficient. The daily dosage should generally be prescribed in 2-3 divided doses.
In primary dysmenorrhoea the daily dosage, which should be individually adapted, is generally 1-3 Emifenac 50 DT.
Children: Because of the dosage strength, Emifenac 50 DT dispersible tablets are not recommended for use in children below 14 years of age.
Emifenac 100 SRT:
Adults: The recommended initial dosage is 1 tablet of Emifenac 100 SRT sustained release tablets.
In milder cases as well as for long-term therapy, 1 tablet of Emifenac 100 SRT is usually sufficient. Where the symptoms are most pronounced during the night or in the morning should preferably be taken in the evening. The tablets should be taken whole with liquid, preferably with meals.
Children: Because of the dosage strength, Emifenac 100 SRT sustained release tablets are not recommended for use in children below 14 years of age.

Contraindications:
Emifenac 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 have been precipitated by aspirin or any other drugs with prostaglandin-synthetase inhibiting activity. Emifenac should be avoided in patients with a history of acute prophyria.
Emifenac 50 DT contains phenylalanine and should not be given to phenylketonurics patients.
-Diclofenac is contraindicated for the treatment of perioperative pain in the setting of coronary artery bypass graft (CABG) surgery.
-Concomitant use of anticoagulants and antiplatelets

Warnings:
-*EMIFENAC 100 SR & EMIFENAC 50 DT* may cause elevation of one or more liver enzymes; close medical surveillance is required when prescribing Diclofenac to patients with impaired hepatic function.
-If abnormal liver function tests persist or worsen, if signs or symptoms consistent with liver disease develop, Diclofenac should be discontinued.
-Physicians should measure transaminases periodically in patients receiving long-term therapy with Diclofenac.Transaminases should be monitored during 4 to 8 weeks after initiating treatment with Diclofenac.
-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 warming symptoms. Elderly patients are at greater risk for serious gastrointestinal events.

Precautions:
-Use of Diclofenac particularly higher doses of 150 mg / day and in prolong treatment may be associated with a slightly increased risk of arterial thrombotic events.
- Patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and / or cerebrovascular disease should only be treated with Diclofenac after careful consideration. Similar consideration should also be made before initiating longer term treatment of patients with risk factors for cardiovascular events.
- As with all types of analgesics, long term use for relief of headache can develop or worsen. Headache caused by over usages of analgesics should not be treated with increased dose of analgesics. In such cases the treatment should be withdrawn.
Emifenac should be used cautiously with the elderly. In patients with congestive heart failure, hypertension, decreased renal or hepatic function, history of gastrointestinal disease or those receiving anticoagulants.
Emifenac 50 DT is recommended for short-term treatment only.

Use in Pregnancy and Lactation:
Diclofenac 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. Diclofenac is excreted in breast milk, but in quantities so small that no undesirable effects on the infant are to be expected.

Side Effects:
Emifenac is generally well tolerated. The reported adverse effects include gastrointestinal disturbances such as epigastric pain, heartburn, nausea, vomiting, diarrhea, and indigestion. Rarely gastrointestinal bleeding, gastric or intestinal ulcer with or without bleeding or perforation may occur. Fluid retention, liver function disorders, rash and prurtitis have been reported.

Drug Interactions:
Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels which should therefore be monitored frequently.
When given simultaneously with preparations contain digoxin, methotrexate, cyclosporine, sulfonylureas or lithium diclofenac may raise their plasma concentrations.
Like other NSAIDs concomitant administration with beta-blockers may antagonize the hypotensive effect of the beta-blockers.
Concomitant administration of other systemic NSAIDs or corticosteroids may increase the occurrence of side effects.
Patients taking diclofenac and oral anticoagulants should undergo routine blood tests.
Colestipol and cholestyramine induced decrease in absorption of Diclofenac.

Overdosage:
Management of acute poisoning with NSAIDs consists essentially of supportive and symptomatic measures. There is no typical clinical picture associated with overdosage of diclofenac.
The following therapeutic measures should be taken in cases of overdosage:
Absorption should be prevented as soon as possible after the overdosage by means of gastric lavage and treatment with activated charcoal.
Supportive and symptomatic treatment should be given for complications such as hypotension, renal failure, convulsions, gastrointestinal irritation and respiratory depression.
Specific therapy such as forced diuresis, dialysis or haemoperfusion is unlikely to be helpful in accelerating the elimination of NSAIDs because of their high protein binding rate and extensive metabolism.

Presentation:
Emifenac 50 DT dispersible tablets are available in packs of 20 tablets.
Emifenac 100 SRT sustained release tablets are available in pack of 10 tablets.

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

THIS IS A MEDICAMENT

- 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 expert 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

Insert code: LFT 0042 (B) Oct 2010