Front

Osteotec®

(DICLOFENAC SODIUM + MISOPROSTOL)

Tablet

آسٹیوٹیک

COMPOSITION:

Osteotec Tablet 50 mg:

Each tablet contains:

Diclofenac Sodium USP (enteric coated) ..... 50 mg.

Misoprostol..... 200 mcg.

Product Specs.: CCL Pharmaceuticals

Osteotec Tablet 75 mg:

Each tablet contains:

Diclofenac Sodium USP (enteric coated) ..... 75 mg.

Misoprostol..... 200 mcg.

Product Specs.: CCL Pharmaceuticals

THERAPEUTIC INDICATIONS:

Osteotec is indicated for acute and chronic treatment of the signs and symptoms of rheumatoid arthritis, osteoarthritis, ankylosing spondylitis, and acute musculoskeletal disorders. Osteotec is a nonsteroidal anti-inflammatory drug (NSAID) with a gastroduodenal mucosal protective component. The Diclofenac Sodium component of Osteotec is effective for the treatment of the signs and symptoms of arthritic conditions. The Misoprostol component of Osteotec is indicated for the prophylaxis of NSAIDs-induced gastric and duodenal ulceration.

DOSAGE AND ADMINISTRATION:

Adults:

For the treatment of the signs and symptoms of rheumatoid arthritis, osteoarthritis and acute musculoskeletal disorders one tablet to be taken with food, two or three times daily. For treatment of the signs and symptoms of ankylosing spondylitis, one tablet to be taken with food two, three or four times daily. Tablets should be swallowed whole, not chewed, crushed, or dissolved.

Elderly/renal impairment/hepatic impairment:

No adjustment of dosage is necessary in the elderly or in patients with hepatic impairment or mild to moderate renal impairment as pharmacokinetics are not altered to any clinically relevant extent. Nevertheless patients with severe renal or hepatic impairment should be closely monitored (see also Adverse Effects section).

Children:

The safety and efficacy of Osteotec in children under the age of 18 years have not been established.

CONTRAINDICATIONS:

Osteotec is contraindicated in patients with active gastrointestinal bleeding. Osteotec should not be used in pregnant women because it induces uterine contractions and therefore has abortifacient potiental. Anecdotal reports, primarily from Brazil, of congenital anomalies and reports of fetal death subsequent to misuse of Misoprostol as an abortifacient never been received. Uterine perforation has been reported with misuse of Misoprostol for cervical ripening or labor induction. Osteotec may cause premature closure of the ductus arteriosus.

SPECIAL WARNING AND SPECIAL PRECAUTIONS:

Serious gastrointestinal toxicity such as bleeding, ulceration, and perforation, have been reported in patients treated with NSAIDs therapy, including Diclofenac Sodium. Physicians and patients should remain alert for ulceration, even in the absence of gastrointestinal symptoms. Women of childbearing potential should be advised not to become pregnant while taking Diclofenac Sodium and to employ adequate contraception while receiving Diclofenac Sodium. If pregnancy is suspected, use of the product should be discontinued. During Diclofenac Sodium therapy, liver function, should be monitored periodically. If Diclofenac Sodium is used in the presence of impaired liver function, close monitoring is necessary. Allergic reactions including anaphylaxis have been reported with NSAIDs, including Diclofenac Sodium and have occurred without prior exposure to the NSAIDs.

In patients with renal, cardiac, or hepatic impairment, caution is required since the use of NSAIDs, including Diclofenac Sodium, may result in deterioration of renal function. Fluid retention and edema have been observed in patients taking NSAIDs, including Diclofenac Sodium. Therefore, Diclofenac Sodium should be used with caution in patients with a history of congestive heart failure or conditions predisposing to fluid retention. NSAIDs, including Diclofenac Sodium, increase platelet aggregation time. Misoprostol does not exacerbate the effects of Diclofenac Sodium on platelet activity. Diclofenac Sodium / Misoprostol has not been studied in children.

Pregnancy:

Contraindicated (see contraindications).

Lactation:

Osteotec should not be administered during breast feeding.

DRUG INTERACTIONS:

Diclofenac Sodium is displaced from its binding sites by aspirin, resulting in lower plasma concentrations peak plasma levels, and AUC values. Therefore, concomitant administration of Osteotec and aspirin is not recommended. Elevated digoxin levels have been reported in patients receiving digoxin and Diclofenac Sodium. Patients receiving digoxin and Osteotec should be monitored for possible digoxin toxicity. NSAIDs may attenuate the natriuretic effect of diuretics. Since concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels, serum potassium should be monitored. Caution should be taken when administering Osteotec with such agents. Some NSAIDs, have been shown to interact with oral anticoagulants, although Diclofenac Sodium has not been shown to interact with anticoagulants of the warfarin type. Therefore, patients receiving concurrent therapy with Osteotec should be monitored to ensure that no change in anticoagulant dosage is required.

Diclofenac Sodium does not alter glucose metabolism in normal subjects, and the effects of oral hypoglycemic agents were not altered by the concomitant administration of Diclofenac Sodium. However there have been reports of changes in the effects of oral hypoglycemic agents in the presence of NSAIDs. Therefore, Osteotec should be administered with caution in patients receiving insulin or oral hypoglycemic agents. Caution is advised when methotrexate is administered concurrently with NSAIDs, including Diclofenac Sodium, because NSAIDs administration may result in increased plasma levels of methotrexate. Diclofenac Sodium decreases lithium renal clearance and increases lithium plasma levels. Therefore, Osteotec should be administered with caution in patients receiving lithium. Antacids may delay the absorption of Diclofenac Sodium. Magnesium-containing antacids have been shown to exacerbate Misoprostol-associated diarrhea.

ADVERSE EFFECTS:

Gastrointestinal:

Abdominal pain, constipation, diarrhea, duodenitis, dyspepsia, eructation, esophagitis, flatulence, gastritis, nausea, and vomiting. Abdominal pain and diarrhea were generally transient and mild to moderate in severity, occurring early in the course of therapy, and lasting several days. The abdominal pain and diarrhea usually resolved spontaneously while continuing Osteotec.

Liver: Clinically significant elevations of SGPT, SGOT, alkaline phosphatase of bilirubin have been observed in association with Osteotec without symptomatic evidence of hepatic disease.

Kidney:

As a class NSAIDs have been associated with renal pathology such as papillary necrosis, interstitial nephritis nephritic syndrome and renal failure.

Female reproductive system:

Breast pain, dysmenorrhea, intermenstrual bleeding, menorrhagia menstrual disorders, uterine cramping, vaginal bleeding (including postmenopausal bleeding), and vaginitis.

Other adverse effects:

Headache, dizziness, skin rashes, pruritis, purpura, bulous eruption, urticaria, angioedema, changes in mood, edema, dyspnea, hepatitis, pancreatitis, stomatitis and thrombocytopenia. In very rare cases, blurred vision, insomnia, nightmares, and mucocutaneous reactions. Allergic reactions including anaphylaxis may occur. In general, the adverse event profile of Diclofenac Sodium / Misoprostol in patients 65 years of age and older was similar to that of younger patients. The only clinically relevant differences were that patients 65 years of age and older appeared to be less tolerant to the gastrointestinal effects of Diclofenac Sodium / Misoprostol given three times a day (t.i.d.), and female patients 65 years of age and older reported fewer reproductive disorders.

OVERDOSAGE:

The toxic dose of Osteotec has not been determined. However, signs of overdosage from the components of the product have been described. Clinical signs that may indicate Diclofenac Sodium overdose include gastrointestinal complaints, confusion, drowsiness or general hypotonia. Clinical signs that may indicate Misoprostol overdose are sedation, tremor, convulsions, dyspnea, abdominal pain, diarrhea, fever, palpitations, hypotension or bradycardia.

Symptoms of Osteotec overdosage should be treated with supportive therapy. In case of acute overdosage, gastric lavage is recommended. Induced diures is may be beneficial because Diclofenac Sodium and Misoprostol metabolites are excreted in the urine. The effect of dialysis on the elimination of Diclofenac Sodium (99% protein bound) and Misoprostol acid (less than 90% protein bound) remains unproven. The use of oral activated charcoal may help to reduce the absorption of Osteotec.

INSTRUCTIONS:

- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

Osteotec Tablet 50 mg	:	Pack of 2 x 10 tablets.
Osteotec Tablet 75 mg	:	Pack of 2 x 10 tablets.

ہدایات:

۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔

گرمی، دھوپ اور نمی سے بچائیں۔

بچوں کی پہنچ سے دور رکھیں۔

صرف ڈاکٹر کے نسخہ پر فروخت کریں۔

FOR FURTHER INFORMATION PLEASE CONTACT:

CCL

Manufactured by:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

1283-B
25066-0001-005-0000-0000