ARTHROTEC®

Presentation

White, round, biconvex, tablets marked AAAA on one side and SEARLE 1411 on the other side. Each tablet consists of an enteric-coated core containing 50 milligrams diclofenac sodium surrounded by an outer mantle containing 200 micrograms misoprostol.

Excipients are: lactose, microcrystalline cellulose, maize starch, povidone K-30, cellulose acetate phthalate, diethyl phthalate, methylhydroxypropylcellulose, crospovidone, magnesium stearate, hydrogenated castor oil, colloidal anhydrous silica.

Uses

Indications

Arthrotec is indicated for acute and chronic treatment of the signs and symptoms of rheumatoid arthritis and osteoarthritis.

Arthrotec is indicated for patients who require a non-steroidal anti-inflammatory drug (NSAID) together with misoprostol.

The diclofenac component of Arthrotec is indicated for the treatment of osteoarthritis and rheumatoid arthritis. The misoprostol component of Arthrotec is indicated for the prophylaxis of NSAID-induced gastric or duodenal ulceration.

Actions

Arthrotec is a nonsteroidal anti-inflammatory drug (NSAID) with a gastroduodenal mucosal protective component.

Dosage and Administration

Adults

One tablet to be taken with food, two or three times daily.
Tablets should be swallowed whole, not chewed.

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 Arthrotec in children has not been established.

Contraindications

Arthrotec is contraindicated in patients with active gastrointestinal bleeding.

Arthrotec is contraindicated in pregnant women and in women planning a pregnancy as it may increase uterine tone and contractions in pregnancy which could produce miscarriage. Also it may cause premature closure of the ductus arteriosus.

Arthrotec is contraindicated in patients with a known hypersensitivity to diclofenac, aspirin, other NSAIDs, misoprostol or other prostaglandins.

Warnings

Use in pre-menopausal women (see also Contraindications). Arthrotec should not be used in pre-menopausal women unless they use effective contraception and have been advised of the risks of taking the product if pregnant. (see Contraindications).

Precautions

Use in patients with known gastric or duodenal ulceration should be avoided.

If NSAID therapy is still thought to be essential then Arthrotec may be considered. However gastric and duodenal ulceration has been reported although less frequently than with diclofenac alone and use of Arthrotec should be under close supervision.

Arthrotec, in common with other NSAIDs, may decrease platelet aggregation and prolong bleeding time. This effect should be considered when bleeding times are determined.

Fluid retention and oedema have been observed in patients taking NSAIDs, including Arthrotec. Therefore, Arthrotec should be used with caution in patients with compromised cardiac function or conditions predisposing to fluid retention.

In patients with renal, cardiac 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.

All patients who are receiving long-term treatment with NSAIDs should be monitored as a precautionary measure (e.g. renal, hepatic function and blood counts).

Drug Interactions

NSAIDs may attenuate the natriuretic efficacy of diuretics due to inhibition of intrarenal synthesis of prostaglandins. Concomitant treatment with potassium-sparing diuretics may be associated with increased serum potassium levels, hence serum potassium should be monitored.

Steady state plasma lithium and digoxin levels may be increased.

Pharmacodynamic studies with diclofenac have shown no potentiation of oral hypoglycaemic and anticoagulant drugs, however as interactions have been reported with other NSAIDs, caution and adequate monitoring are nevertheless advised. (see Precautions).

Caution is advised when methotrexate is administered concurrently with NSAIDs because of possible enhancement of its toxicity by the NSAID as a result of increase in methotrexate plasma levels.

Pregnancy

Contraindicated. (see Contraindications).

Lactation

Arthrotec should not be administered during breast feeding.

Adverse Effects

Gastrointestinal: abdominal pain, diarrhoea, nausea, dyspepsia, flatulence, vomiting, gastritis, constipation and eructation. Diarrhoea is usually mild to moderate and transient and can be minimised by taking Arthrotec with food and by avoiding the use of predominantly magnesium-containing antacids.

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

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

Female reproductive system: Menorrhagia, intermenstrual bleeding and vaginal bleeding have been reported in pre-menopausal women, and vaginal bleeding in post-menopausal women.

Other adverse effects: Headache, dizziness, skin rashes. Rarely, with NSAIDs, allergic reactions including anaphylaxis may occur.

Overdosage

The toxic dose of Arthrotec has not been determined and there is no experience of overdosage. Intensification of the pharmacological effects may occur with overdose. Management of acute poisoning with NSAIDs essentially consists of supportive and symptomatic measures. It is reasonable to take measures to reduce absorption of any recently consumed drug by forced emesis, gastric lavage or activated charcoal.

Pharmaceutical Precautions

Store in a dry place at or below 25°C

Package Quantities

Blister packs of 20 tablets

SEARLE

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