

Fastaid 50mg & 75mg

(Diclofenac sodium)

Fastaid SR

(Diclofenac sodium)

WARNING: RISK OF SERIOUS CARDIOVASCULAR AND GASTROINTESTINAL EVENTS

Cardiovascular Thrombotic Events

Non-steroidal anti-inflammatory drugs (NSAIDs), including diclofenac, may increase the risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke, which may be fatal. This risk may occur early during treatment and may increase with duration of use. Diclofenac should not be administered in the setting of coronary artery bypass graft (CABG) surgery.

Gastrointestinal Bleeding, Ulceration and Perforation

NSAIDs, including diclofenac, may cause serious gastrointestinal adverse events including bleeding, ulceration and perforation of the stomach or intestines, which may be fatal. These events may occur at any time during treatment and without warning symptoms. Elderly patients and patients with a previous history of peptic ulcer disease and/or gastrointestinal bleeding are at greater risk.

COMPOSITION

Fastaid 50 mg

Each enteric coated tablet contains:

Diclofenac Sodium 50 mg

Product Complies B.P Specifications.

Fastaid 75 mg

Each enteric coated tablet contains:

Diclofenac Sodium 75 mg

Product Complies B.P Specifications.

Fastaid SR 100 mg

Each sustained release tablet contains:

Diclofenac Sodium 100 mg

Product Complies B.P Specifications.

DESCRIPTION

Diclofenac sodium is a non-steroidal anti-inflammatory drug with analgesic, anti-inflammatory and antipyretic properties. Its pharmacological action is associated with inhibition of cyclooxygenase (COX-1 and COX-2) and subsequent reduction in prostaglandin synthesis.

INDICATIONS

Fastaid tablets are indicated for the relief of signs and symptoms associated with:

Osteoarthritis.

Rheumatoid arthritis.

Ankylosing spondylitis.

The lowest effective dose for the shortest duration consistent with individual treatment requirements should be used.

DOSAGE AND METHOD OF ADMINISTRATION

After assessing the risk/benefit ratio in each individual patient, the lowest effective dose for the shortest possible duration should be used.

The dose and frequency should be adjusted according to the individual patient's response to treatment.

Fastaid 50 mg and Fastaid 75 mg

Osteoarthritis:

The recommended daily dose is 100–150 mg in divided doses, administered as 50 mg twice or three times daily, or 75 mg twice daily.

Rheumatoid arthritis:

The recommended daily dose is 150–200 mg in divided doses, administered as 50 mg three or four times daily, or 75 mg twice daily.

Ankylosing spondylitis:

The recommended daily dose is 100–125 mg, administered as 25 mg four times daily, with an additional 25 mg dose at bedtime if necessary.

Fastaid SR 100 mg

Osteoarthritis:

The recommended dose is 100 mg once daily.

Rheumatoid arthritis:

The recommended dose is 100 mg once daily. In patients where 100 mg once daily is unsatisfactory, the dose may be increased to 100 mg twice daily if the benefits are considered to outweigh the increased risk of adverse effects.

Different formulations of diclofenac are not necessarily bioequivalent even when the milligram strength is the same.

CONTRAINDICATIONS

Known hypersensitivity to diclofenac or any component of the formulation.

History of asthma, urticaria or other allergic-type reactions following administration of aspirin or other NSAIDs.

Use in the setting of coronary artery bypass graft (CABG) surgery.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Cardiovascular Effects

NSAIDs may increase the risk of serious cardiovascular thrombotic events, including myocardial infarction and stroke. The risk may increase with higher doses and longer duration of treatment.

The lowest effective dose should be used for the shortest possible duration. Caution is required in patients with cardiovascular disease or risk factors for cardiovascular disease.

Gastrointestinal Effects

Diclofenac may cause gastrointestinal inflammation, ulceration, bleeding and perforation, which may occur with or without warning symptoms.

The risk is increased with increasing age, previous history of peptic ulcer disease or gastrointestinal bleeding, prolonged NSAID therapy and concomitant use of corticosteroids, anticoagulants, aspirin, SSRIs or SNRIs.

Concomitant administration of more than one NSAID should be avoided.

Hepatic Effects

Elevations in hepatic transaminases may occur during treatment with diclofenac. Severe hepatic reactions, including hepatitis, liver necrosis and liver failure, have been reported.

Patients receiving long-term treatment should have hepatic function monitored periodically. Diclofenac should be discontinued if abnormal liver tests persist or worsen, or if clinical signs and symptoms suggestive of liver disease develop.

Hypertension

Diclofenac may cause new onset of hypertension or worsening of pre-existing hypertension. Blood pressure should be monitored during initiation and throughout treatment.

Heart Failure and Oedema

Fluid retention and oedema have been reported with NSAID therapy. Diclofenac should be used with caution in patients with heart failure and in patients receiving diuretics, ACE inhibitors or angiotensin receptor blockers.

Use should be avoided in patients with severe heart failure

unless the expected benefits outweigh the potential risks.

Renal Effects

NSAIDs may cause renal injury, particularly in patients with impaired renal function, dehydration, hypovolaemia, heart failure, liver dysfunction, elderly patients and those receiving diuretics, ACE inhibitors or angiotensin receptor blockers. Renal function should be monitored in patients at increased risk of renal impairment.

Anaphylactic Reactions

Serious allergic reactions, including anaphylactic reactions, may occur with diclofenac. Particular caution is required in patients with a history of hypersensitivity reactions to aspirin or other NSAIDs.

Asthma Related to Aspirin Sensitivity

Diclofenac is contraindicated in patients with aspirin-sensitive asthma. Patients with pre-existing asthma without known aspirin sensitivity should be monitored for worsening of asthma symptoms.

Serious Skin Reactions

Serious skin reactions, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis, may occur with NSAID therapy. Treatment should be discontinued at the first appearance of skin rash or any other sign of hypersensitivity.

Haematological Effects

Diclofenac may inhibit platelet aggregation and prolong bleeding time. Patients receiving anticoagulants or antiplatelet therapy should be monitored for signs of bleeding.

Pregnancy

Diclofenac should not be used during the third trimester of pregnancy. NSAID use from approximately 20 weeks of pregnancy may be associated with fetal renal dysfunction and oligohydramnios, while use from approximately 30 weeks may cause premature closure of the fetal ductus arteriosus.

If treatment is considered necessary during pregnancy, the lowest effective dose for the shortest duration should be used.

Lactation

Diclofenac may be present in human milk. The benefit of breastfeeding should be considered together with the mother's clinical need for diclofenac and any potential effects on the breastfed infant.

Effects on Ability to Drive and Use Machines

Patients experiencing visual disturbances, dizziness, drowsiness or other central nervous system effects during treatment should refrain from driving or operating machinery.

DRUG INTERACTIONS

Concomitant administration of diclofenac with other NSAIDs or salicylates is not recommended due to increased gastrointestinal toxicity.

Particular caution is required with concomitant use of:

Anticoagulants and antiplatelet agents.

Aspirin.

Corticosteroids.

SSRIs and SNRIs.

ACE inhibitors, angiotensin receptor blockers and beta-blockers.

Diuretics.

Digoxin.

Lithium.

Methotrexate.

Cyclosporine.

Pemetrexed.

CYP2C9 inhibitors or inducers.

Patients receiving these medicines concomitantly should be appropriately monitored.

ADVERSE EFFECTS

Adverse reactions reported with diclofenac include:

Common:

Abdominal pain, constipation, diarrhoea, dyspepsia, flatulence, heartburn, nausea, vomiting, dizziness, headache, oedema, elevated liver enzymes, pruritus, rash and tinnitus.

Less common:

Hypertension, tachycardia, heart failure, gastrointestinal ulceration or bleeding, gastritis, hepatitis, jaundice, anaemia, thrombocytopenia, drowsiness, somnolence, vertigo, asthma, dyspnoea, renal impairment and photosensitivity.

Rare:

Anaphylactic reactions, myocardial infarction, arrhythmia, hypotension, colitis, pancreatitis, liver failure, aplastic anaemia, agranulocytosis, renal failure, convulsions, angioedema, Stevens-Johnson syndrome, toxic epidermal necrolysis and other serious skin reactions.

OVERDOSE

Symptoms following acute NSAID overdose may include lethargy, drowsiness, nausea, vomiting and epigastric pain. Gastrointestinal bleeding, hypertension, acute renal failure, respiratory depression and coma may occur in severe cases.

Treatment is symptomatic and supportive. There is no specific antidote. Activated charcoal and other measures may be considered following a significant overdose, as clinically appropriate. Haemodialysis or forced diuresis may not be useful due to the high degree of protein binding.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic Properties

Diclofenac possesses analgesic, anti-inflammatory and antipyretic properties. Its mechanism of action involves inhibition of cyclooxygenase enzymes and reduction of prostaglandin synthesis.

Pharmacokinetic Properties

Diclofenac is extensively absorbed following oral administration and is highly bound to plasma proteins. It undergoes extensive hepatic metabolism, principally involving CYP2C9, followed by urinary and biliary excretion of metabolites.

The terminal half-life of unchanged diclofenac is approximately 2 hours.

STORAGE

Store below 30°C in a dry place, protect from light.

To be dispensed on the prescription of a registered medical practitioner only.

Keep out of the reach of children.

PRESENTATION

Fastaid 50 mg: Available in blister pack of 2 × 10's.

Fastaid 75 mg: Available in blister pack of 2 × 10's.

Fastaid SR: Available in blister pack of 3 × 10's.

خوراک: ڈاکٹر کی ہدایت کے مطابق استعمال کریں۔

دوا کو ۳۰ ڈگری سینٹی گریڈ سے کم درجہ حرارت پر خشک جگہ پر رکھیں،
روشنی سے بچائیں۔ صرف رجسٹرڈ ڈاکٹر کے نسخے پر فروخت کریں۔
بچوں کی پہنچ سے دور رکھیں۔

Note: Product contains lactose.

نوٹ: پروڈکٹ میں لکٹوز شامل ہے۔

Manufactured by:

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