Focus on K-Fenak Anti-Inflammatory® tablets

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Introduction

Diclofenac was discovered in 1973 and is one of the most widely prescribed nonsteroidal anti-inflammatory drugs (NSAIDs) globally.[1] It is commonly used in the management of an array of conditions including painful musculoskeletal disorders, rheumatism, dysmenorrhoea, acute attacks of gout, migraine attacks and fever.[2-4] Due to their role as opioid-sparing agents, NSAIDs can be used as part of a multimodal pain management strategy to reduce the need for opioids.[4,5]

Diclofenac potassium contains the same active ingredient, diclofenac, as diclofenac sodium; hence, the pharmacological, safety and toxicology profiles are expected to be similar for the two salts.[4]

Both the therapeutic and side-effects of diclofenac can be attributed to its ability to inhibit an enzyme called cyclooxygenase (COX) which is essential for the production of prostaglandins.[1,2,4-7]

Non-selective NSAIDs, such as diclofenac, inhibit both COX-1 and COX-2 enzymes:[1,2,4]

- COX-2 enzymes are primarily involved in the production of prostaglandins that play a major role in inflammatory processes and the resulting pain.[2-4,6] By inhibiting COX-2, diclofenac decreases the production of prostaglandins leading to its anti-inflammatory, analgesic, and antipyretic effects.[1-3]
- COX-1 enzymes are involved in the production of prostaglandins that help to protect the gastric mucosa from harmful acidity. COX-1 enzymes also play a role in maintaining normal activity of platelets and kidney perfusion, among other processes.[1,6] Inhibition of COX-1 is responsible for some of the side-effects associated with NSAIDs, such as gastrointestinal (GI) upsets, bleeding and ulceration.[2,3]

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Indications, dosage and administration

Each tablet contains 50 mg of diclofenac potassium. Tablets should be taken whole with water, preferably at mealtimes.[2] Peak plasma levels of diclofenac are reached within 20 to 60 minutes.[2] The rate of absorption of diclofenac from immediate-release tablets containing the potassium salt is faster than that from the enteric-coated tablet containing the sodium salt. The extent of absorption, however, is comparable.[4]

The table below outlines the recommended dosage ranges for adult patients for each clinical indication, including both initial and maximum daily doses. Dosage should always be individualised based on the patient's condition and response to treatment. The lowest effective dose should be used for the shortest duration possible.[2,3]

Efficacy

Diclofenac potassium has been evaluated for its efficacy in relieving pain and inflammation associated with various

Table I: Recommended dosage ranges for K-Fenac Anti-Inflammatory tablets® per indication[2]

Indication	Recommended daily dosage for adults (given in 2–3 divided doses)	Maximum Daily Dose
Inflammatory and degenerative forms of rheumatism • Rheumatoid arthritis • Ankylosing spondylitis • Osteoarthrosis • Spondylarthritis Painful musculoskeletal conditions Non-articular rheumatism Acute attacks of gout Mild to moderately painful postoperative and post-traumatic inflammation and swelling Pain following dental surgery	Initially: 100 to 150 mg/day. In milder cases, and for long-term use, lower doses may be adequate	150 mg/day
Primary dysmenorrhoea	Initially: 50 to 150 mg/day Adjusted individually	If needed, increase dose over the course of several menstrual cycles up to a maximum of 200 mg/day

conditions. Below are a few examples, discussing the efficacy of diclofenac potassium in various settings.[3,4]

Pain

Diclofenac potassium (50 or 100 mg, followed by 50 mg every eight hours) was as effective as naproxen sodium (550 mg, followed by 275 mg every eight hours) in relieving postoperative orthopaedic surgery pain.[3]

Diclofenac potassium (150 mg daily) was more effective than placebo and at least as effective as piroxicam (20 mg daily) or ibuprofen (1,2 g daily) when used to relieve orthopaedic pain.[3]

A single oral dose of diclofenac potassium (50 and 100 mg) has been found to be as effective as a single dose of aspirin (650 mg) in patients with dental extraction or gynaecological surgery pain. It also appears that the duration of the analgesic effect of diclofenac potassium is longer than that of aspirin.[3]

Dysmenorrhoea

Diclofenac potassium (50–100 mg, followed by 50 mg every eight hours) was effective for moderate to severe dysmenorrhoea, showing comparable efficacy to naproxen sodium (550 mg; followed by 275 mg every eight hours).[3,4]

Migraine

Diener HC et al., 2006, evaluated the efficacy of 50 mg diclofenac potassium tablets compared with placebo in patients with migraine pain. The onset of analgesic effect was 60 min for the tablet.[8] At two hours after the intake of:

- The tablet, 18.5% (55/298) were pain free and 41.6% (124/298) had a headache response.
- Placebo, 11.7% (35/299) were pain free and 21.4% (72/299) had a headache response.[8]

The diclofenac tablet was also more effective than placebo in reducing the percentage of patients experiencing migraine-associated symptoms such as nausea, photophobia, phonophobia.[2,3,8]

Safety considerations

Contraindications

Contraindications for K-Fenak Anti-Inflammatory® (tablets) include:[2,4]

- Hypersensitivity to diclofenac or any of the ingredients in the tablet
- History of asthma, urticaria or allergic-type reactions induced by aspirin or other NSAIDs (i.e. asthma, angioedema, urticaria, acute rhinitis, nasal polyps or atopy)
- GI perforation, ulceration or bleeding (peptic ulcer bleeds ([PUBs]). This includes those with active disease, history of PUBs as well as those with a history of PUBs following previous use of NSAIDs (including diclofenac)
- Heart failure, ischaemic heart disease (angina), cerebrovascular disease (stroke) or peripheral arterial disease (reduced blood flow to limbs)
- Porphyria
- Pregnancy and breastfeeding
- Children under 14 years of age
- Renal or hepatic failure

Side-effects, precautions and special considerations

The risk of side-effects increases with increasing doses and duration of treatment. The lowest effective dose should be used, for the shortest duration possible, especially in elderly and frail patients. The elderly are more susceptible to a variety of side-effects from NSAIDs.[2-5]

Side-effects and special precautions pertaining to the gastrointestinal tract, haematological, cardiovascular, and renal system are briefly discussed below.[2,4]

Gastrointestinal (GI) side-effects

Common side-effects include dyspepsia, nausea, vomiting, diarrhoea, abdominal pain, flatulence and anorexia.[2] Serious side-effects include GI bleeding, perforation or peptic ulcers.[3] The risk of GI side-effects increases with age or history of prior PUBs. However, side-effects can occur at any time while using diclofenac, with or without warning signs or symptoms.[3-5]

Co-therapy with proton pump inhibitors (PPIs) or misoprostol could be considered for high-risk patients.[2,5] Patients should be advised to consult the doctor immediately if they experience any signs and symptoms suggestive of serious GI side-effects such as bloody or black tarry stools or vomiting blood. Treatment should be discontinued if GI bleeding or ulceration occurs.[2]

Haematological side-effects

NSAIDs inhibit platelet aggregation and may prolong bleeding time in some patients. Caution and monitoring are recommended for patients who may be adversely affected by such an action, for example, those suffering from haemophilia, platelet disorders or those on anticoagulants.[2,4]

Cardiovascular and cerebrovascular side-effects

NSAIDs are associated with an increased risk of cardiovascular events including myocardial infarction, stroke or thrombotic events.[2,4]

Patients with pre-existing cardiovascular or cerebrovascular disease or those with significant risk factors for cardiovascular events (e.g. hypertension, hyperlipidaemia, diabetes mellitus, smoking) may be at greater risk. Diclofenac should only be used after thorough assessment of the risks and benefits for these patients.[2,4]

Patients should be advised to consult the doctor immediately if they experience any signs and symptoms suggestive of a serious

arteriothrombotic event, such as chest pain, shortness of breath, weakness or slurring of speech.[2,-4]

Renal side-effects

NSAIDs may impair renal function and may promote sodium retention which can lead to fluid retention and oedema.[2-5]

NSAIDs should be used with caution in patients with impaired cardiac or renal function, history of hypertension, the elderly, patients receiving concomitant treatment with diuretics or medicines that can significantly impact renal function.[2,4,5]

The potential risk for renal damage is increased in the presence of dehydration.[5] Patients should be reminded to stay hydrated when using NSAIDs as dehydration increases the risk of kidney damage.[5]

Interactions

Concomitant use of two or more NSAIDs should be avoided as there is no additional benefit. In addition, concomitant use may lead to increased side-effects or severe toxicity.[3,5]

Diclofenac also has the potential to interact with various other medicines which could lead to altered drug levels, reduced therapeutic efficacy or increased toxicity amongst others. In addition, gastrointestinal irritation may be aggravated with concomitant use of alcohol.[4,5]

Safety considerations listed in this article are not all-inclusive. Please refer to the package insert for additional information regarding dosing, side-effects, interactions, special precautions, contraindications, and monitoring instructions.

Important prescribing points

- The lowest effective dose should be used for the shortest duration possible. This is, however, especially important when NSAIDs are prescribed for elderly patients, frail patients and for those who are more prone to side-effects.[2-5]
- Long-term use of NSAIDs, regardless of COX-selectivity, may increase the risk of cardiovascular side-effects.[2,4,5]
- To protect against NSAID-related gastrointestinal side-effects, a PPI or misoprostol may be considered for those susceptible to these side-effects.[2,3,5]
- The risk-benefit should be assessed when using diclofenac in patients with underlying medical conditions that may increase their risk of side-effects and/or when there is a potential for drug-drug-interactions.[3,5]
- Patients should be educated about potentially serious side-effects and what action to take should they occur.[3]

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