Catafast®
(diclofenac potassium)
50 mg powder for oral solution

Malta

Basic Succinct Statement

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Presentation:
Catafast powder for oral solution in sachets of 50 mg diclofenac potassium.

Indications:
Short-term treatment in the following acute conditions: post-traumatic pain, inflammation and swelling, e.g. due to sprains, post-operative pain, inflammation and swelling, e.g. following dental or orthopaedic surgery, painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis, migraine attacks, painful syndromes of the vertebral column, non-articular rheumatism, as an adjuvant in severe painful inflammatory infections of the ear, nose or throat.

Dosage:
Dose to be individually adjusted, lowest effective dose to be given for the shortest duration.
**Adults:** 50 to 150 mg daily in divided doses. For dysmenorrhoea and migraine attacks: up to 200 mg daily. **Adolescents aged 14 and over:** 50 to 100 mg daily in divided doses up to 150mg daily. **Children and adolescents below 14 years of age:** not recommended.

Contraindications:
Active gastric or intestinal ulcer, bleeding or perforation; known hypersensitivity to diclofenac or to any of the excipients, to aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs); Patients in whom attacks of asthma, urticaria, or acute rhinitis are precipitated by acetylsalicylic acid or other NSAIDs; last trimester of pregnancy; severe hepatic, renal or cardiac failure.

Precautions/warnings:
Avoid use with other systemic NSAIDs including COX-2 inhibitors. Risk of gastrointestinal (GI) bleeding, perforation or serious allergic reactions, persistent abnormal liver and renal function tests; to be discontinued if these conditions occur. Risk of allergic reactions. May mask signs and symptoms of infection. Caution recommended in patients with symptoms/history of GI disease, asthma, seasonal allergic rhinitis, chronic pulmonary diseases, chronic infections of the respiratory tract, elderly or impaired hepatic function (including porphyria), ulcerative colitis or Crohn’s disease. Caution when used concomitantly with corticosteroids, anticoagulants, anti-platelets agents or SSRIs. Caution while driving or using machines. Combined use with protective agents to be considered in patients with history of ulcers, elderly, and those requiring low dose aspirin. Monitoring of liver function and blood counts recommended during prolonged treatment. Monitoring of renal function recommended in patients with history of hypertension, impaired cardiac or renal function, extracellular volume depletion, the elderly, patients treated with diuretics or drugs that impact renal function. Monitoring recommended in patients with defects of haemostasis. As Catafast contains a source of phenylalanine, may be harmful for patients with phenylketonuria. Beware of severe fluid retention and oedema. Very rarely reported serious skin reactions, some of them fatal, including exfoliative dermatitis, Stevens-Johnson syndrome and toxic epidermal necrolysis. Discontinue at the first appearance. May be associated with a small increased risk of arterial thrombotic events. Before treatment consider carefully patients with uncontrolled hypertension, congestive heart failure, established ischaemic heart disease, peripheral arterial disease, and/or cerebrovascular disease, and before initiating longer-term treatment of patients with risk factors for cardiovascular disease. **Pregnancy and lactation:** Should not be used in the first and second trimester of pregnancy and by breast-feeding mothers. Not recommended to use in women attempting to conceive as it may impair female fertility. Should not be administered during breast feeding in order to avoid undesirable effects in the infant.
Interactions:
Caution with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs. Monitoring recommended for patients receiving anticoagulants, anti-platelet agents as well as blood glucose level if used concomitantly with antidiabetics. Monitoring of serum lithium and digoxin levels recommended if used concomitantly. Dose of diclofenac to be reduced in patients receiving ciclosporin. Interactions with concomitant use of quinolones antibacterials.

Adverse reactions:
Common undesirable effects are: Headache, dizziness, vertigo, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia, transaminases increased, rash.

Rare undesirable effects are: Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnoea), gastritis, gastrointestinal haemorrhage, haematemeses, melaena, diarrhoea hemorrhagic, gastrointestinal ulcer (with or without bleeding or perforation), hepatitis, jaundice, liver disorder, urticaria, oedema.

Very rare undesirable effects are: Thrombocytopenia, leukopenia, anaemia (including haemolytic anaemia and aplastic anaemia), agranulocytosis, angioneurotic oedema (including face oedema), disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, paraesthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, taste disturbances, cerebrovascular accident, visual disturbance, vision blurred, diplopia, tinnitus, hearing impaired, palpitations, chest pain, cardiac failure, myocardial infarction, hypertension, vasculitis, pneumonitis, colitis (including haemorrhagic colitis and exacerbation of ulcerative colitis or Crohn’s disease), constipation, stomatitis, glossitis, oesophageal disorder, diaphragm-like intestinal strictures, pancreatitis, fulminant hepatitis, bullous eruptions, eczema, erythema, dermatitis multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), dermatitis exfoliative, loss of hair, photosensitivity reaction, purpura, allergic purpura, pruritus, acute renal failure, haematuria, proteinuria, nephritic syndrome, interstitial nephritis, renal papillary necrosis.

Marketing Authorisation number:
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Marketing Authorisation Holder:
Novartis Pharmaceuticals UK Ltd., Frimley Business Park, Frimley, Camberley, Surrey GU16 7 SR, UK.

Please refer to Summary of Product Characteristics (SmPC) before prescribing.

Full prescribing information is available on request from Novartis Pharma, P.O. Box 124, Valletta, VLT 1000, Malta. Tel +356 22983217.

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