

Catafast 50 mg powder for oral solution

Presentation: *Diclofenac potassium*: powder for oral solution in sachets of 50 mg.

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. Not recommended in children and adolescents below 14 years of age.

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); 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; 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, 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. 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. Combined use with protective agents to be considered in patients with history of ulcer, elderly, and those requiring low dose aspirin.

Monitoring of liver function and blood counts recommended during prolonged period.

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 defect of haemostasis. As Catafast contains a source of phenylalanine, may be harmful for patients with phenylketonuria. Beware of severe fluid retention and oedema.

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, haematemesis, melaena, diarrhoea haemorrhagic, 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, erythema 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.

Packs and prices: Country specific.

Note: Before prescribing please read full prescribing information.