Cataflam BSS [1]

Important note: Before prescribing, please consult full prescribing information.

Dosage and administration: Dose to be individually adjusted. Adverse effects may be minimized by using the lowest effective dose for the shortest duration necessary.

Adults: 50 to 150 mg/day in divided doses (dysmenorrhea and migraine attacks: up to 200 mg/day). **Adolescents over 14 years:** 50 to 100 mg/day, with maximum daily dose of 150 mg. **Children over 1 year and adolescents:** 0.5 to 2 mg/kg/day, with a maximum daily dose of 150 mg.

For INJ: 1 or at the most 2 ampoules (I.M.) per day for not more than 2 days (for adults only). Total maximum daily dose of 150 mg. The directions for intramuscular injection must be followed in order to avoid damage to a nerve or other tissue at the injection site.

Special patient populations: Patients with established heart disease or cardiovascular risk factors should only receive doses up to max. 100 mg daily if treated for more than 4 weeks.

Contraindications: Known hypersensitivity to diclofenac, to sodium metabisulphite (***INJ only***) or other excipients. Active gastric or intestinal ulcer, bleeding or perforation. Last trimester of pregnancy. epatic failure. Renal failure (GFR <15 mL/min/1.73m2). Severe cardiac failure. Known hypersensitivity to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs). Proctitis (***SUP only***).

Warnings and precautions: Caution recommended in patients with symptoms/history of gastrointestinal (GI) disease and in elderly because of the risks of GI bleeding or perforation. To be discontinued if these conditions occur. Combined use with protective agents to be considered in patients with history of ulcer, elderly and those requiring low dose acetylsalicylic acid. Caution when used concomitantly with corticosteroids, anticoagulants, anti-platelet agents or SSRIs. ?Caution recommended in patients with ulcerative colitis or Crohn's disease. Treatment generally not recommended in patients with established heart disease or uncontrolled hypertension. If needed in patients with established heart disease, uncontrolled hypertension or significant cardiovascular risk factors, treat only after careful consideration and with dose adjustment and periodic re-evaluation, especially when treatment continues for more than 4 weeks. Monitoring of blood counts recommended during prolonged treatment. Monitoring recommended in patients with defects of haemostasis. Caution recommended in patients with asthma, seasonal allergic rhinitis or chronic pulmonary diseases. Special caution recommended for parenteral use in patients with bronchial asthma (***INJ only***). Risks of serious allergic reactions. To be discontinued if these conditions occur. Caution recommended in patients with impaired hepatic function (including porphyria). Monitoring of liver function during prolonged treatment. Beware of severe fluid retention and edema. 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. Caution is indicated in the elderly. Avoid use with other systemic NSAIDs including COX-2 inhibitors. May mask signs and symptoms of infection.

Pregnancy and breast-feeding: Must not be used during the third trimester of pregnancy. Should not be used in the first and second trimester of pregnancy and by breast-feeding mothers.

Fertility: Not recommended to use in women attempting to conceive as it may impair female fertility.

Excipients: Possibility of hypersensitivity reactions to sodium metabisulphite (***INJ only***).

Adverse drug reactions: ?**Common undesirable effects are:** Headache, dizziness, vertigo, nausea, vomiting, diarrhea, dyspepsia, abdominal pain, flatulence, decreased appetite, transaminases increased, rash, application site irritation (***SUP only***). (***INJ only***): injection site reaction, injection site pain, injection site induration.

Uncommon* undesirable effects are: myocardial infarction, cardiac failure, chest pain, palpitations (*frequency reflects data from long-term treatment with a high dose of 150 mg/day).

Rare undesirable effects are: Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnea), gastritis, gastrointestinal hemorrhage, hematemesis, hemorrhagic diarrhea, melena, gastrointestinal ulcer (with or without bleeding, gastrointestinal stenosis or perforation, which may lead to peritonitis), hepatitis, jaundice, liver disorder, urticaria, edema, injection site necrosis (INJ only), proctitis (***SUP only***).

Very rare undesirable effects are: Thrombocytopenia, leukopenia, anemia (including hemolytic anemia and aplastic anemia), agranulocytosis, angioedema (including face edema), disorientation, depression, insomnia, nightmare, irritability, psychotic disorder, paresthesia, memory impairment, convulsion, anxiety, tremor, aseptic meningitis, dysgeusia, cerebrovascular accident, visual impairment*, blurred vision*, diplopia*, tinnitus, impaired hearing, hypertension, vasculitis, pneumonitis, colitis (including hemorrhagic colitis, ischemic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, esophageal disorder, intestinal diaphragm disease, pancreatitis, fulminant hepatitis, hepatic necrosis/hepatic failure, bullous dermatitis, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), exfoliative dermatitis, alopecia, photosensitivity reaction, purpura, Henoch-Schonlein purpura, pruritus, acute kidney injury (acute renal failure), hematuria, proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis, hemorrhoids (***SUP only***), injection site abscess (***INJ only***).

***Visual effects:** If symptoms of visual disturbances occur during diclofenac treatment, an ophthalmological examination may be considered to exclude other causes.

Frequency not known: Kounis syndrome

Interactions: Monitoring of serum lithium or digoxin levels recommended if used concomitantly. Caution with concomitant use of diuretics and antihypertensives (e.g. beta blockers, ACE inhibitors), methotrexate, other NSAIDs and corticosteroids, SSRIs).Dose of diclofenac to be reduced in patients receiving ciclosporin or tacrolimus. Monitoring of serum potassium level if used concomitantly with drugs known to cause hyperkalemia (e.g. diuretics, ciclosporin, tacrolimus, trimethoprim. Interactions with concomitant use of quinolone antibacterials, CYP2C9 inhibitors (e.g. voriconazole) and CYP2C9 inducers (e.g. rifampicin). Monitoring recommended for patients receiving anticoagulants, anti-platelet agents as well as blood glucose level if used concomitantly with antidiabetics. Cases of metabolic acidosis have been reported when diclofenac was co-administered with metformin, especially in patients with pre-existing renal impairment. Monitoring of phenytoin plasma concentrations is recommended if used concomitantly.

Packs and prices: Country specific.

Legal classification: Country specific.
