NOVARTIS

CATAFLAM®

(dicofenac potassium)

50mg Tablets

(diclofenac resinate)

15 mg/mL oral drops suspension

Basic Succinct Statement

CODE: BSS RD 22 MAY 19; APPR 26 FEB 20

This material is only meant for Healthcare Professionals

CATAFLAM®

Presentation:

Pharmaceutical form	*Dosage strength(s)*	*Active substance (equivalent to/corresponding to)*	*Abbreviation*
Sugar-coated tablets	50mg	Diclofenac potassium	SCT
Oral drops suspension	15 mg/ mL	diclofenac resinate equivalent to 0.5 mg diclofenac potassium per drop (= 1.5%)	ODS

Indications: Short-term treatment in the following acute conditions:

Post-traumatic and post-operative pain, inflammation and swelling, e.g. due to sprains or following dental or orthopaedic surgery.	SCT, ODS
Painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis.	SCT
Acute migraine attacks. Cataflam should not be used for migraine prophylaxis.	SCT
Painful syndromes of the vertebral column, non-articular rheumatism.	SCT
As an adjuvant in severe painful inflammatory infections of the ear, nose or throat, e.g. pharyngotonsillitis, otitis. In keeping with general therapeutic principles, the underlying disease should be treated with basic therapy, as appropriate. Fever alone is not an indication.	SCT, ODS

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: The initial daily dose is 100 to 150 mg. In milder cases, 75 to 100 mg daily is usually sufficient. The total daily dose should generally be divided in 2 to 3 doses.

Children and adolescents: Cataflam oral drops are particularly suitable for paediatric use, because they enable the dose to be adapted individually to the child's body weight in accordance with the dosage schedule recommended for children (1 drop = 0.5 mg).

Children aged 1 year or over and adolescents should be given 0.5 to 2 mg/kg body weight (1 to 4 drops) daily, depending on the severity of the disorder.

For adolescents aged 14 or over, 75 to 100 mg daily is usually sufficient. The total daily dose should generally be divided in 2 to 3 doses.

Total maximum daily dose of 150 mg.

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

Contraindications: Active gastric or intestinal ulcer, bleeding or perforation; known hypersensitivity to diclofenac or to any of the excipients, to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs); last trimester of pregnancy; hepatic failure; renal

failure (GFR <15 mL/min/1.73m^2); severe cardiac failure; known hypersensitivity to acetylsalicylic acid or other non-steroidal anti-inflammatory drugs (NSAIDs).

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 recommended when used concomitantly with corticosteroids, anticoagulants, anti-platelet agents or SSRIs. Caution recommended in patients with ulcerative colitis or Crohn's disease. Caution recommended when used after gastro-intestinal surgery. Treatment generally not recommended in patients with established heart disease (congestive heart failure, established ischemic heart disease, peripheral arterial disease) or uncontrolled hypertension or significant cardiovascular risk factors (e.g. hypertension, hyperlipidemia, diabetes mellitus and smoking), treat only after careful consideration and whit 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. 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.

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

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

Rare undesirable effects are: Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnoea), gastritis, gastrointestinal haemorrhage, haematemesis, haemorrhagic diarrhoea, melaena, gastrointestinal ulcer (with or without bleeding, gastrointestinal stenosis or perforation, which may lead to peritonitis), 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 impairment*, blurred vision*, diplopia*, tinnitus, impaired hearing, hypertension, vasculitis, pneumonitis, colitis (including haemorrhagic colitis, ischemic colitis and exacerbation of ulcerative colitis or Crohn's disease), constipation, stomatitis, glossitis, oesophageal disorder, intestinal diaphragm disease, pancreatitis, fulminant hepatitis, hepatitis necrosis/hepatic failure, bullous dermatitis, eczema, erythema, erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis (Lyell's syndrome), exfoliative dermatitis, loss of hair, photosensitivity reaction, purpura, Henoch-Schonlein purpura, pruritus, acute kidney injury (including acute renal failure), haematuria, proteinuria, nephrotic syndrome, tubulointerstitial nephritis, renal papillary necrosis.

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

♦**Frequency not known**: Kounis syndrome