NOVARTIS

VOLTAREN® (diclofenac sodium) 75 mg/3 mL Solution for injection
50 mg Gastro-resistant tablets
75 mg and 100 mg Prolonged-release tablets
12.5 mg, 25 mg, and 50 mg Suppositories

Basic Succinct Statement

CODE: BSS RD 22 MAY 19; APPR 29 MAY 20

This material is only meant for Healthcare Professionals

VOLTAREN®

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

Presentation:

Pharmaceutical form	*Dosage strength(s)*	*Active substance (equivalent to/corresponding to)*	*Abbreviation*
Solution for injection	75 mg/3 mL	diclofenac sodium	INJ
Gastro-resistant tablets	50 mg	diclofenac sodium	GRT
Prolonged-release tablets	75 mg and 100 mg	diclofenac sodium	PRT
Suppositories	12.5 mg, 25 mg, and 50 mg	diclofenac sodium	SUP

Indications:

(*) Inflammatory and degenerative forms of rheumatism: rheumatoid arthritis, ankylosing spondylitis.	GRT, PRT, SUP, INJ (I.M.),
(*) Inflammatory and degenerative forms of rheumatism: juvenile rheumatoid arthritis.	GRT, SUP,
(*) Inflammatory and degenerative forms of rheumatism: osteoarthritis and spondylarthritis.	GRT, PRT, SUP, INJ (I.M.)
Inflammatory and degenerative forms of rheumatism: painful syndromes of the vertebral column, non-articular rheumatism.	GRT, PRT, SUP, INJ (I.M.),
Acute attacks of gout.	GRT, SUP, INJ (I.M.),
Post-traumatic and post-operative pain, inflammation and swelling, e.g. following dental or orthopedic surgery.	GRT, PRT, SUP, INJ (I.M.),
Painful and/or inflammatory conditions in gynecology, e.g. primary dysmenorrhea or adnexitis.	GRT, PRT, SUP,
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.	GRT, SUP,
Migraine attacks.	SUP, INJ (I.M.)
Renal colic and biliary colic.	INJ (I.M.)
Treatment or prevention of post-operative pain in a hospital setting (I.V. only).	INJ (I.V.)

(*): “Exacerbation of” for INJ only.

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** only: 1 or at the most 2 ampoules (I.M. or I.V.) daily as initial therapy for not more than 2 days. Ampoules must not be given as an I.V. bolus injection. Before I.V. infusion dilute contents of 1 ampoule with 100 to 500 mL of saline 0.9% or glucose 5% buffered with 0.5 mL sodium bicarbonate 8.4% or 1 mL of 4.2%. 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.

♦For GRT, PRT, SUP. **Adults:** 50 to 150 mg/day in divided doses (dysmenorrhoea and migraine attacks: up to 200 mg/day for GRT, SUP, DIT). **Children over 1 year and** adolescents**:** 0.5 to 2 mg/kg/day (juvenile rheumatoid arthritis up to 3mg/kg/day for GRT, SUP), with a maximum daily dose of 150 mg.

♦**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. ♦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). ♦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 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. If needed in patients with established heart disease, uncontrolled hypertension or significant cardiovascular risk factors (e.g. hypertension, hyperlipidemia, diabetes mellitus and smoking), 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 oedema. ♦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.

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, photosensivity reaction, purpura, Henoch-Schonlein purpura, pruritus, acute kidney injury (including 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