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.

Renal colic and biliary colic.

**Dosage:**
Dose to be individually adjusted, lowest effective dose to be given for the shortest duration.
- (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.
- (For SCT, SUP, ODS, OS) Adults: 50 to 150 mg/day in divided doses (dysmenorrhoea and migraine attacks: up to 200 mg/day). Adolescents over 14 years: 75 to 100 mg/day, with maximum daily dose of 150 mg (for SCT only). Children over 1 year and adolescents: 0.5 to 2 mg/kg/day, with a maximum daily dose of 150 mg.

**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 antiinflammatory drugs (NSAIDs); last trimester of pregnancy; severe hepatic, renal or cardiac failure; proctitis (SUP only). Known hypersensitivity to sodium metabisulphite (ampoules).

**Warnings/Precautions:**
- Avoid use with other systemic NSAIDs including COX-2 inhibitors.
- Risks 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.

**Presentation:**

<table>
<thead>
<tr>
<th>Pharmaceutical form</th>
<th>Dose strength(s)</th>
<th>Active substance (equivalent to/corresponding to)</th>
<th>Abbreviation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solution for injection</td>
<td>75 mg/3 mL</td>
<td>diclofenac potassium</td>
<td>INJ</td>
</tr>
<tr>
<td>Sugar-coated tablets</td>
<td>25 mg and 50 mg</td>
<td>diclofenac potassium</td>
<td>SCT</td>
</tr>
<tr>
<td>Suppositories</td>
<td>12.5 mg, 25 mg and 75 mg</td>
<td>diclofenac potassium</td>
<td>SUP</td>
</tr>
<tr>
<td>Oral suspension</td>
<td>1.8 mg/mL</td>
<td>diclofenac potassium</td>
<td>OS</td>
</tr>
<tr>
<td>Oral drops suspension</td>
<td>15 mg/mL, diclofenac resinate equivalent to 0.5 mg diclofenac potassium per drop (=1.5%)</td>
<td>ODS</td>
<td></td>
</tr>
</tbody>
</table>

**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.
- Painful and/or inflammatory conditions in gynaecology, e.g. primary dysmenorrhoea or adnexitis.
- Migraine attacks.
- Painful syndromes of the vertebral column, non-articular rheumatism.
Common undesirable effects are:
Headache; dizziness, vertigo, nausea, vomiting, diarrhoea, dyspepsia, abdominal pain, flatulence, anorexia, transaminases increased, rash, application site irritation (SUP only). (INJ only): injection site reaction, injection site pain, injection site induration.

Rare undesirable effects are:
Hypersensitivity, anaphylactic and anaphylactoid reactions (including hypotension and shock), somnolence, asthma (including dyspnoea), gastritis, gastrointestinal haemorrhage, haematemesis, diarrhoea haemorrhagic, melaena, gastrointestinal ulcer (with or without perforation), hepatitis jaundice, liver disorder, urticaria, oedema, injection site necrosis (INJ only), proctitis (SUP only).

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, hepatic necrosis/hepatic failure, bullos 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, nephrotic syndrome, interstitial nephritis, renal papillary necrosis, haemorrhoids aggravated (SUP only), injection site abscess (INJ only).

Packs and prices: Country specific.
Legal classification: Country specific.