MONOGRAPH

PARECOXIB

Scope (Staff):	Medical, Pharmacy, Nursing, Anaesthetic Technicians
Scope (Area):	All Clinical Areas

Child Safe Organisation Statement of Commitment

CAHS commits to being a child safe organisation by applying the National Principles for Child Safe Organisations. This is a commitment to a strong culture supported by robust policies and procedures to reduce the likelihood of harm to children and young people.

This document should be read in conjunction with this DISCLAIMER

QUICKLINKS

Dosage/Dosage Adjustments | Administration | Compatibility | Monitoring

DRUG CLASS

Selective COX-2 inhibitor Nonsteroidal Anti-Inflammatory drug (NSAID) [1]

INDICATIONS AND RESTRICTIONS

For prescription under the direction of a Consultant Anaesthetist or Acute Pain Service as a single dose to non cardiac patients over 2 years of age undergoing significantly painful surgery and where oral administration of NSAIDs is not appropriate due peri–operative restriction of oral intake.

- Short term treatment of postoperative pain [1]
- Pain due to inflammation where enteral medications are not tolerated [1]

CONTRAINDICATIONS

- Hypersensitivity to parecoxib, valdecoxib, sulfonamides or any component of the formulation [1,8]
- Severe hepatic impairment [1,4,5]
- Increased risk of cardiovascular events – e.g., those with ischaemic heart disease, peripheral arterial disease or cerebrovascular disease[1]
- Active peptic ulcer disease or gastrointestinal (GI) bleeding [1,4,8]
- Severe heart failure or post major vascular surgery (e.g. coronary artery bypass graft) [1,4, 5]

PRECAUTIONS

- Inflammatory bowel disease (IBD) – may worsen pre-existing IBD. Use with caution.[5, 19, 20]
- History of gastrointestinal bleeding or high risk of gastrointestinal adverse effects (e.g. use of corticosteroids, anticoagulants, SSRIs) – higher risk of serious GI complications. Avoid use or proceed with extreme caution; consider adding a proton pump inhibitor.[1,3,4,5,8]
- Heart failure – may worsen due to salt and fluid retention. Avoid use in moderate cases.[1,3,5]
- Hypertension – may cause new or worsening hypertension. Monitor blood pressure closely.[3,4,5,8]
- History of myocardial infarction, stroke or other thrombotic events – associated with increased risk of death, recurrent MI and serious cardiovascular events, particularly with long term use. Avoid use where possible. [1, 3, 4, 5]
- Renal impairment, dehydration, or concomitant use with ACE inhibitors and diuretics (triple therapy) may increase the risk of renal dysfunction or acute failure – avoid use if possible or start at the lowest recommended dose with monitoring. Ensure adequate hydration before initiating therapy.[1,3,4,5,8]
- Hepatic impairment – exposure is increased. Reduce dose in moderate impairment and avoid use in severe impairment. [1, 4, 5]
- Concomitant use with oral anticoagulants (e.g. warfarin, apixaban, dabigatran, rivaroxaban) – increased risk of bleeding. Monitor closely, particularly during the first few days of initiating or changing parecoxib dose; check INR if on warfarin. [3,4]
- Asthma – may increase risk of bronchospasm (lower risk with COX-2 selective NSAIDs), particularly in aspirin-sensitive asthma. Use with caution. [3, 5, 21, 22, 23]
- History or suspicion of serious skin reactions (e.g. SJS, TEN, bullous eruptions) or DRESS syndrome – avoid use. Discontinue immediately if signs appear. [3,4,5]

FORMULATIONS

Listed below are products available at PCH, other formulations may be available, check with pharmacy if required:

- Parecoxib 40 mg Vial

Imprest location: Formulary One

DOSAGE & DOSAGE ADJUSTMENTS

Dosing in Overweight and Obese Children: Dose based on ideal body weight [16,24,25,26,27]

Intravenous/Intramuscular:[4]

May be used as:

- A **single perioperative** dose [2,16,17,18]
- Every **12–24 hours postoperatively** (maximum 40 mg in 24 hours) [13,16,17]

≥ 2 years:

- 10 – < 15 kg: 0.9 mg/kg every 12 – 24 hours.
- 15 – < 25 kg: 0.8 mg/kg every 12 – 24 hours. Maximum 40 mg in 24 hours.
- 25 – 40 kg: 0.7 mg/kg every 12 – 24 hours. Maximum 40 mg in 24 hours.
- > 40 kg: 0.6 mg/kg every 24 hours. Maximum 40 mg in 24 hours.

Alternatively, some clinicians round off to a single dose of **1 mg/kg** (maximum 40 mg) for simplicity.[2]

- Separate the next NSAID dose (e.g. ibuprofen, celecoxib, diclofenac) by at least 12 hours.[12,16, 17]
- Parenteral therapy should be discontinued once oral therapy tolerated. For a suitable oral agent consult the AMH Children's Dosing Companion or a clinical pharmacist.

Renal impairment:

- Avoid use if possible or start at the lowest recommended dose [1,3,4,5,6]

Hepatic impairment:

- No dosage adjustment required for mild hepatic impairment.[3]
- Half the usual recommended dose in patients with moderate hepatic impairment. [3,4,5]
- Contraindicated in severe impairment.[1,3,4,5]

RECONSTITUTION & ADMINISTRATION

PREPARATION:

- Reconstitute the vial with 2 mL of Sodium Chloride 0.9%, glucose 5% or glucose 5% in sodium chloride 0.45%. Resulting concentration of 20 mg/mL [9,14]

ADMINISTRATION:

IV Injection:

- Inject undiluted as a rapid injection over a few seconds. [1,9,14]

Intramuscular:

- Give undiluted by slow, deep IM injection [1,9,14]
- See Intramuscular (IM) Injections.

Subcutaneous:

- Not routinely recommended. May be given as an intermittent subcutaneous injection or continuous subcutaneous infusion in palliative care settings. [9,14]

COMPATIBILITY *(LIST IS NOT EXHAUSTIVE)*

Compatible fluids: [9,14]

- Glucose 5%
- Glucose 5% and sodium chloride 0.45%
- Sodium chloride 0.9%

Compatible at Y-site: [9,14]

- Hartmann's
- Plasma-Lyte 148

Only commonly used drugs are listed below. This is not a complete list of incompatible drugs. Compatibilities of IV drugs must be checked when two or more drugs are given concurrently.

INCOMPATIBLE drugs:

- Ondansetron [15]

MONITORING

Monitoring may not be required in patients using parecoxib for short term use. For patients on long-term parecoxib therapy, monitor the following:

- Baseline and annual checks of complete blood count, haemoglobin, BP, weight, creatinine, and liver function are advised for chronic use.[1,3, 4, 8]
- Symptoms of gastrointestinal bleeding.[1,3,8]
- Blood pressure and renal function in dehydrated patients and patients on prolonged treatment. [3,4,8]

ADVERSE EFFECTS

Common: Nausea, dyspepsia, GI ulceration or bleeding, raised liver enzymes. diarrhoea, headache, dizziness, salt and fluid retention, hypertension [1,3,4,5,12]

Infrequent: Oesophageal ulceration, heart failure, hyperkalaemia, renal impairment, confusion, bronchospasm, rash [1,4,5]

Rare: Blood dyscrasias, interstitial nephritis, cystitis, nephrotic syndrome, acute renal failure, papillary necrosis, myocardial infarction, stroke, severe hypotension, pulmonary embolism, deep vein thrombosis, hepatitis, aseptic meningitis, tinnitus, photosensitivity, severe skin reactions (e.g.

Stevens-Johnson syndrome, toxic epidermal necrolysis), hypersensitivity (e.g. anaphylaxis, asthma, angioedema, urticaria) [1]

STORAGE

Vial: Store below 25°C. Protect from light.[14]

Reconstituted solution: Stable for 24 hours at 25°C. Do not refrigerate or freeze.[14]

INTERACTIONS

This medication may interact with other medications; consult PCH approved references (e.g. Clinical Pharmacology), a clinical pharmacist or PCH Medicines Information Service on extension 63546 for more information.

Please note: The information contained in this guideline is to assist with the preparation and administration of **Parecoxib**. Any variations to the doses recommended should be clarified with the prescriber prior to administration

Related CAHS internal policies, procedures and guidelines

- Analgesia and Sedation in Paediatric Critical Care
- Tonsillectomy and Adeno-tonsillectomy Post-operative Management
- Assessment of Acute Pain in Infants, Children, and Adolescents
- Intramuscular (IM) Injections

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