Emerging Drug List

PARECOXIB SODIUM

Generic (Trade Name): Parecoxib sodium
Manufacturer: Pharmacia & Upjohn Inc.
Indication: For peri-operative pain relief

Current Regulatory Status: Parecoxib is currently under review at Health Canada and the Food and Drug Administration in the U.S. They are expecting approval in the fourth quarter of 2001. It is not marketed in any country at this time

Description: Parecoxib is the first parenteral cyclooxygenase-2 (COX-2) selective inhibitor to be developed. It is a water-soluble prodrug that is rapidly hydrolyzed to valdecoxib (the active COX-2 inhibitor). Valdecoxib’s affinity for COX-2 versus COX-1 is 90 times greater than celecoxib and 34,000 times greater than ketorolac. Once injected, peak concentrations of valdecoxib are attained in 10 to 20 minutes. Valdecoxib has a half-life of eight to 10 hours.

Current Treatment: Currently, the only other nonsteroidal anti-inflammatory agent that is available as an injection is ketorolac. Ketorolac is used in some centres for peri-operative pain management, however opioids are the main class of agents used for this indication. Ketorolac has been associated with a relatively high incidence of gastrointestinal (GI) side effects, including severe cases of hemorrhage.

Cost: There is no information available on the cost of parecoxib.

Evidence: Parecoxib has been compared to ketorolac and morphine in clinical trials. Parecoxib at a dose of 20 and 40 mg/day IV, were compared to ketorolac, 30 mg/day IV and morphine, 4 mg/day or placebo in 202 women undergoing hysterectomy. Both doses of parecoxib were comparable to ketorolac for relieving postoperative pain. Both treatments were significantly better than morphine, although the morphine dose was too low to be clinically effective.

Parecoxib 20 or 40 mg/day IV was compared to ketorolac 30 mg/day IV and morphine 4 mg/day in a post orthopedic surgery study. The results showed that both doses of parecoxib were comparable to ketorolac and both agents were superior to morphine.

Parecoxib 80 mg/day was as effective as ketorolac 120 mg/day in relieving pain in 45 patients who underwent general abdominal surgery. Both agents were superior to placebo.

Adverse Effects: Parecoxib 40 mg/day IV was compared to ketorolac 30 mg/day IV in 232 patients to evaluate their adverse effects on the GI tract. The incidence of endoscopically-proven GI erosion was 38/116 (33%) with ketorolac and 1/116 (< 1%) with parecoxib. Also parecoxib did not affect platelet aggregation, while ketorolac significantly inhibited platelet aggregation.

Parecoxib did not interact with anesthetic agents including propofol and midazolam.
Conclusion: Parecoxib has the potential to significantly alter the method in which pain in the perioperative patient is treated. Opioids are currently the main means of alleviating pain in these patients, but they are commonly associated with significant side effects. Parecoxib appears to be as effective as ketorolac; however, it causes less adverse effects. Further comparative clinical trials with standard doses of opioids are needed to clarify parecoxib’s true role in perioperative patients.

References:

The contents of this bulletin are current as of May 2001. This series highlights medical technologies that are not yet in widespread use in Canada and that may have a significant impact on health care. The contents are based on information from early experience with the technology; however, further evidence may become available in the future. These summaries are not intended to replace professional medical advice. They are compiled as an information service for those involved in planning and providing health care in Canada.

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