

LOCAL OPERATING PROCEDURE - CLINICAL

Approved Safety & Quality Committee May 2021 Review May 2023

PARECOXIB SODIUM INJECTION (DYNASTAT INJECTION)

INDICATIONS

For a single peri-operative dose for the management of post-operative pain.

PHARMACODYNAMICS

Following injection, parecoxib sodium is rapidly converted to valdecoxib. The in vivo pharmacology of parecoxib is therefore that of valdecoxib. The mechanism of action of valdecoxib is by inhibition of cyclooxygenase-2 (COX-2) mediated prostaglandin synthesis.

When given at the recommended doses for management of acute pain, the onset of analgesia is 7-14 minutes and reaches a peak effect within 2 hours. After a single dose, the duration for analgesia ranges from 6 to greater than 24 hours.

CONTRAINDICATIONS

Parecoxib is contraindicated in patients with known hypersensitivity to parecoxib sodium or valdecoxib.

Parecoxib should not be given to patients who have experienced asthma, urticaria, or allergic-type reactions after taking aspirin, NSAID's or other COX-2 specific inhibitors. Severe, rarely fatal, anaphylactoid-like reactions are possible in such patients.

Paracoxib is a Cat C in pregnancy and is contraindicated.

SPECIAL WARNINGS AND PRECAUTIONS (Please seek advice from medical/surgical/O&G team)

Gastrointestinal (GI) Effects - Risk of GI Ulceration, Bleeding, and Perforation

Significantly fewer endoscopically detected ulcers are seen with parecoxib compared to ketorolac and naproxen, and with valdecoxib compared to ibuprofen and naproxen.

Nevertheless, physicians and patients should remain alert for ulceration and bleeding even in the absence of symptoms. Parecoxib should be prescribed with caution in patients with a prior history of ulcer disease or gastrointestinal bleeding.

Hepatic Effects

A patient with symptoms and/or signs suggesting hepatic dysfunction, or in whom an abnormal liver function test has occurred, should be evaluated for evidence of the development of a hepatic reaction while on therapy with parecoxib. If clinical signs and symptoms consistent with hepatic disease develop, or if systemic manifestations occur (e.g. eosinophilia, rash, etc.) parecoxib should be discontinued.

Renal Effect

Clinical trials with valdecoxib have shown renal effects similar to those observed with comparator NSAIDS.

Caution should be used when initiating treatment in patients with considerable dehydration. It is advisable to rehydrate patients first and then start therapy with parecoxib.

Patients with poor urine output particularly pre-eclamptic women with impaired renal function i.e. serum creatinine >70umol/l. It is reasonable for RN/RM to withhold NSAIDs if a patient has poor urine output.

Patients with poorly controlled hypertension particularly post-natal women with pre-eclampsia.

Royal HOSPITAL FOR WOMEN

LOCAL OPERATING PROCEDURE - CLINICAL

Approved Safety & Quality Committee May 2021 Review May 2023

PARECOXIB SODIUM INJECTION (DYNASTAT INJECTION) cont'd

Patients may be trialled on NSAIDs if they are asthmatic but have received aspirin or other NSAID previously without exacerbation to their asthma.

Concomitant use of anti-platelet agents e.g. aspirin >600mg/day, clopidogrel, dipyridamole

Age >65 years: the risk and severity of NSAID associated side effects is increased in elderly people.

NSAIDs should only be given in pregnancy if the maternal benefits outweigh the potential fetal risks, at the lowest effective dose and for the shortest duration possible. Please seek advice from O&G medical team prior to prescribing NSAIDs for a pregnant woman.

ADMINISTRATON

Reconstitute the vial with 2 mL of sodium chloride 0.9% or glucose 5%.

Administer a single 40mg dose as an IV bolus over a few seconds or as a deep IM injection.

INCOMPATABILITIES

Do not reconstitute the vial with water for injection as this can cause precipitation.

RISK RATING

High

NATIONAL STANDARD

Medication

REFERENCES

- 1. MIMS online 2020. Full prescribing information for Parecoxib sodium. Last updated 19/2/2020
- 2. Australian Injectable Drugs Handbook 8th Edition, Society of Hospital Pharmacists of Australia Content last updated 7/2/2020

REVISION & APPROVAL HISTORY

Reviewed and endorsed Therapeutic & Drug Utilisation Committee 28/4/21

Approved Quality & Patient Care Committee 16/2/17

Reviewed and endorsed Therapeutic & Drug Utilisation Committee 13/12/16

Approved Quality & Patient Safety Committee 18/12/14

Previous title Parecoxib Sodium 40MG powder and diluent for injection (Dynastat Injection 40MG)

Reviewed and endorsed Therapeutic & Drug Utilisation Committee 9/12/14

Approved Quality & Patient Safety Committee 15/7/10

Reviewed and Endorsed Therapeutic & Drug Utilisation Committee 20/4/10

Dynastat Injection 40MG Approved Quality Council 18/11/02

FOR REVIEW: MAY 2023