

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.

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 (eg. 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. .

Caution is also recommended in patients with pre-existing renal disease.

Use in Pregnancy: Pregnancy Category: C

Use of parecoxib during pregnancy is not recommended.

CLINICAL POLICIES, PROCEDURES & GUIDELINES

Approved by Quality & Patient Care Committee
16/2/17

PARECOXIB SODIUM INJECTION (DYNASTAT INJECTION) cont'd

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.

INCOMPATIBILITIES

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

REFERENCES

1. MIMS online 2016. Full prescribing information for Parecoxib sodium. Last updated 1/10/2016
Accessed 7/12/2016
2. Australian Injectable Drugs Handbook 6th Edition, Society of Hospital Pharmacists of Australia
Content last updated 23/8/2016

REVISION & APPROVAL HISTORY

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 : DECEMBER 2019