PARECOXIB (DYNASTAT)

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The Bureau of Food and Drugs would like to announce, after a careful review, the re-introduction of Parecoxib (Dynastat) into the Philippine market.

The following reasons justify the said action:

1. Demonstrated efficacy for short-term (< 3 days) pain control after dental, general, gynecologic and orthopedic surgeries

2. Use of parecoxib decreases demand for opioid analgesics (based on study comparing morphine and ketorolac) by 20-40%

3. Currently approved for marketing in Australia, Singapore and the European Union

4. Rare occurrence of serious skin reactions like Stevens-Johnson Syndrome (SJS) and Toxic Epidermal Necrolysis (TEN)

For Parecoxib, the BFAD would hereby recommend the following:

1. Maximum duration of Dynastat administration to not more than 3 days

2. Limit the use in hospitals.

3. Availability in hospital pharmacies only

4. Its use under immediate physician supervision (anesthesiologist/surgeon)

5. Company to conduct postmarketing surveillance study for 3 more years

6. Safety measures that should be instituted and use of checklist to implement these measures before Dynastat can be given:

a. As for patient screening, the conditions that are listed below constitute absolute contraindications (also reflected in the black box warning of the package insert)

- Coronary Artery Bypass Graft (CABG) patients
- Stroke
- Myocardial infarction
- Congestive Heart Failure (CHF) NYHA II-IV
- Uncontrolled Hypertension

b. Also for inclusion in the checklist, under contraindications (also in Section 4.3 of the Summary of Product Characteristics)

- History of hypersensitivity to the active substance or any of the excipients

- History of previous serious allergic drug reaction of any type especially cutaneous reactions like SJS and TEN, erythema multiformae as well as allergy to sulphonamides
- Active peptic ulcer or gastrointestinal bleeding
- Patients who have had bronchial asthma, nasal polyps, and angioneurotiedema
- Allergic-type reactions (like urticaria, brochospasm/asthma and acute rhinitis) after taking acetylsalicylic acid or NSAIDS including COX-2 inhibitors
- Peripheral arterial disease
- Third trimester of pregnancy and breast-feeding
- Established ischemic heart disease
- Severe hepatic dysfunction
- Inflammatory bowel disease

7. Added safety measure of doing skin test
8. Revision of package insert including black box warning
9. Advise to healthcare professionals to exercise caution in prescribing Dynastat in patients with risk factors for heart disease like hypertension, hyperlipidemia, diabetes and smoking
10. Dear Doctor letters addressed to doctor-users

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