Information Exchange System

Alert No. 106

Risk of serious hypersensitivity and skin reactions with parecoxib sodium

The European Medicines Evaluation Agency (EMEA) has issued a public statement on parecoxib sodium (Dynastat/Rayzon/Xapit) concerning the risk of serious hypersensitivity and skin reactions. This statement is based on the fact that serious reactions including Stevens-Johnson syndrome, toxic epidermal necrolysis, erythema multiforme and exfoliative dermatitis as well as anaphylaxis and angioedema have occurred with valdecoxib and that these reactions cannot be ruled out for parecoxib, the prodrug of valdecoxib. Some of the reactions have occurred in patients with a history of allergic type reactions to sulfonamides.

The EMEA statement reflects the following:

- Physicians should note that parecoxib sodium (Dynastat/Rayzon/Xapit) is contraindicated in patients with a history of hypersensitivity to sulfonamides
- Patients with known allergic reactions to sulfonamides may be prone to, and should be aware of the possibility of, severe side effects with parecoxib sodium (Dynastat/Rayzon/Xapit)

Parecoxib sodium is currently approved as a short-term treatment of post-operative pain in Mexico and in Europe (including all 15 European Union member states). Relevant changes to the prescribing and patient information of parecoxib are available in the European Public Assessment Report of Dynastat/Rayzon/Xapit on the EMEA website.

References: