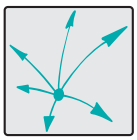

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# Etoricoxib: a French review of adverse effects

● **Peripheral oedema, and serious gastrointestinal, cardiovascular and cutaneous disorders.**

*Etoricoxib* is a nonsteroidal anti-inflammatory drug (NSAID) said to selectively target cyclo-oxygenase-2. It has been marketed in France since 2010, for the treatment of osteoarthritis pain, despite having more adverse effects than other NSAIDs (1,2).

The Clermont-Ferrand Regional Pharmacovigilance Centre in France reviewed adverse effects attributed to *etoricoxib* between March 2010 and March 2012, based on data from the French pharmacovigilance system and the company that markets the drug (3).

The authors analysed 311 adverse effects that occurred in 207 patients with an average age of 63 years, 132 (64%) of whom were women. Half of the patients had taken *etoricoxib* for osteoarthritis, while the others were prescribed *etoricoxib* for off-label indications.

Adverse effects included renal disorders (5 cases of acute renal failure, 3 cases of nephrotic syndrome), cardiovascular events (35 cases of oedema, 22 cases of arterial hypertension, 7 cases of congestive heart failure, 14 arterial or venous thrombotic disorders), gastrointestinal disorders (including 3 gastrointestinal bleeds and 2 uncomplicated ulcers), 12 hypersensitivity reactions, and one case of toxic epidermal necrolysis (3). Two patients died.

**In practice.** When NSAID therapy is contemplated, it is best to use the well-documented drugs *ibuprofen* and *naproxen*, at the lowest effective dose. The marketing of *etoricoxib* exposes patients to more harms than benefits.

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**Selected references from Prescrire's literature search.**

**1-** Prescrire Editorial Staff "Etoricoxib. Avoid using cox-2 inhibitors for pain" *Prescrire Int* 2007; **16** (92): 223-227.

**2-** Prescrire Editorial Staff "Approval of etoricoxib is unacceptable!" *Prescrire Int* 2010; **19** (108): 158.

**3-** Chenaf C et al. "Post-marketing surveillance of Arcoxia° (etoricoxib) safety: a 2-year follow-up in France" 34th Pharmacovigilance Meeting, Angers: 22-24 April 2013. *Fundamental Clin Pharmacol* 2013; **27** (suppl. 1): 105 (abstract P2-134).

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# Pregabalin: cardiac adverse effects

● **Rhythm and conduction disorders, heart failure, even at low doses.**

*Pregabalin* is a gamma-amino butyric acid (GABA) analogue closely related to *gabapentin*. It is used to treat neuropathic pain, generalised anxiety disorder, and partial seizures (1,2). Its adverse effect profile includes psychiatric disorders, abuse and addiction, gastrointestinal disorders, weight gain, skin rash, liver damage, visual field defects, and haematological disorders (1,3). Cases of heart failure have also been reported (1).

The Fernand-Widal Regional Pharmacovigilance Centre in Paris analysed 41 reports of cardiac adverse effects attributed to *pregabalin* in the French pharmacovigilance database (4).

**Especially when used for neuropathic pain.** The 26 women and 15 men concerned had a median age of 74 years and were mainly taking *pregabalin* for neuropathic pain. The cardiac adverse effects consisted of 25 cases of arrhythmia or conduction disorders (bradycardia, tachycardia, atrioventricular block, atrial fibrillation), 13 cases of heart failure, 5 cases of palpitations, and one myocardial infarction. Twenty-six of these cardiac adverse effects were considered severe (4).

**Often less than 150 mg per day.** The median dose of *pregabalin* was 100 mg per day, which is less than the 150 mg to 600 mg per day recommended in the *pregabalin* summary of product characteristics (2,4).

Time to onset was known in 59% of cases, and was a median of 9 days (4).

Outcome was known in 35 cases: 30 patients recovered and 3 "were improving". Two patients died: a 77-year-old woman died of cardiac decompensation, and a 58-year-old man of myocardial infarction (he was also taking *gemcitabine* and *cisplatin*). Thirty-two of the 41 patients had a history of heart disorders (4).

**In practice.** When a patient taking *pregabalin* develops a cardiac disorder, the possible role of this drug should be considered, and *pregabalin* withdrawal may be warranted, especially in patients with a history of heart disease.

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**Selected references from Prescrire's literature search.**

**1-** Prescrire Rédaction "12-1-11. Patients sous gabapentine ou prégabaline" *Rev Prescrire* 2012; **32** (350 suppl. interactions médicamenteuses).

**2-** European Commission "SPC-Lyrica° 25 mg capsules" 3 June 2013: 203 pages.

**3-** Prescrire Rédaction "Prégabaline: des effets indésirables graves à surveiller" *Rev Prescrire* 2008; **28** (301): 833.

**4-** Martinez I et al. "Cardiac events and pregabalin: spontaneous reports notified to the French pharmacovigilance database" 34th Pharmacovigilance Meeting, Angers: 22-24 April 2013. *Fundamental Clin Pharmacol* 2013; **27** (suppl. 1): 95 (abstract P 2-086).