Translated from ***Rev Prescrire*** **January 2009; 29 (303): 9**

duloxetine

NEW INDICATION

In generalised anxiety too? No thanks!

● **No tangible efficacy but numerous and sometimes severe adverse effects.**



NOT ACCEPTABLE

Duloxetine has now been approved in the EU for the treatment of generalised anxiety, even though it has not been compared with a short course of benzodiazepine treatment (1). In 4 randomised double-blind trials lasting about 10 weeks, the difference between the *duloxetine* and placebo groups only varied from 2 to 5 points on the 56-point Hamilton Anxiety Scale (primary endpoint) (1). Although statistically significant, these differences are unlikely to have much clinical relevance. In addition, there was an average drop-out rate of about 40% in these trials (1).

Duloxetine is a serotonin and noradrenaline reuptake inhibitor that carries an even higher risk of adverse effects and interactions than "selective" serotonin reuptake antidepressants (see below) (1).

In practice, when psychological approaches to generalised anxiety prove inadequate, it is better to avoid using *duloxetine* and to use a short course of benzodiazepine treatment instead, in the absence of a better alternative (2).

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Selected references from Prescrire's literature search.



Following our request for information, Lilly did not provide us with any information.

1- European Medicines Agency - CHMP "European Public Assessment Report (EPAR) (rev. 8) - Cymbalta. Scientific discussion H-572-II-27" 28 July 2008: 27 pages.
2- "Anxiety disorders". In: "Martindale The Complete Drug Reference" The Pharmaceutical Press, London. www.medicinescomplete.com accessed 17 September 2008: 2 pages.

duloxetine

(CYMBALTA°)

Capsules

• **30 mg** or **60 mg** of *duloxetine* per capsule

■ **New indication:** *"Treatment of generalised anxiety disorder".*
[EU marketing authorisation, centralised procedure]

antidepressant; serotonin and noradrenaline reuptake inhibitor



Editors' Opinion

Psychopanacea?

Lilly is doing everything possible to make *duloxetine* profitable, in indications as varied as stress urinary incontinence, depression, neuropathic pain, and now generalised anxiety (see above) (1,2). *Duloxetine* is also currently under evaluation in chronic low back pain, knee osteoarthritis, and fibromyalgia (see *Prescrire International* issue 99, page 14) (3,4).

But does this psychotropic drug really represent a panacea?

A closer look at the evidence shows that the opposite is true (1-3): efficacy is uncertain, while adverse effects are numerous and sometimes serious. Like "selective" serotonin reuptake inhibitors (SSRIs), *duloxetine* can cause neuropsychological, gastrointestinal and sexual disorders. There is also a dose-dependent increase in blood pressure due to the noradrenergic effects (the drug is contraindicated in hypertensive patients) (5). The risk of liver damage has been known for years, as have the many potential drug interactions due to pharmacokinetic interference or to additive adverse effects of a convulsive, haemorrhagic, serotonergic or sympathomimetic nature (6,7). *Duloxetine* should not be used during pregnancy (8). The European packaging also raises concerns about treatment safety: the tablets are not sold in unit blister packs, and the multilingual film cover is difficult to decipher. Finally, far cheaper generic versions of serotonin reuptake inhibitors are available.

We have come to expect this type of behaviour from profit-seeking drug companies. What we find unacceptable is the way in which the regulatory authorities are passively allowing this growing "medication of existence". Patients and healthcare professionals should simply avoid using this drug, which represents anything but a panacea!

Prescrire

Rev Prescrire 2009; 29 (303): 9.

1- Prescrire Rédaction "duloxétine-Yentreve°. Dans l'incontinence urinaire d'effort : trop de risques pour trop peu de bénéfices" *Rev Prescrire* 2005 ; **25** (263) : 491-494 + **28** (300) : II de couv.
2- Prescrire Rédaction "duloxétine-Cymbalta°. Dépression, neuropathies diabétiques : trop d'effets indésirables" *Rev Prescrire* 2006 ; **26** (274) : 486 (version complète sur le site www.prescrire.org : 6 pages).
3- Prescrire Rédaction "duloxétine-Cymbalta°. À éviter aussi dans la fibromyalgie" *Rev Prescrire* 2008 ; **28** (300) : 730.
4- Lilly "Lilly clinical trial registry" Site internet www.lillytrials.com consulté le 20 octobre 2008 : 5 pages.
5- Prescrire Rédaction "Duloxétine : nouvelle contre-indication" *Rev Prescrire* 2007 ; **27** (285) : 505.
6- Prescrire Rédaction "Duloxétine : atteintes hépatiques" *Rev Prescrire* 2005 ; **25** (267) : 829.
7- Prescrire Rédaction "22-1-3. Patients sous duloxétine" *Rev Prescrire* 2008 ; **28** (302 suppl. interactions médicamenteuses).
8- European Medicines Agency - CHMP "European Public Assessment Report (EPAR) (rev. 8) - Cymbalta. Scientific discussion H-572-II-27" 28 juillet 2008 : 27 pages.

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