

Stress urinary incontinence drug's benefits do not outweigh harms

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A new study indicates that the benefits of duloxetine, a drug used in Europe to treat stress incontinence in women, do not outweigh the harms. The article is published in *CMAJ* (*Canadian Medical Association Journal*).

Duloxetine, a drug approved in Canada, the US and Europe to treat major depression, is approved in Europe to treat stress urinary incontinence—involuntary leakage of urine during exertion, sneezing or coughing—that affects an estimated 1 in 10 women.

The US Food and Drug Administration has noted a higher-than-expected rate of suicide attempts in open-label extensions of controlled trials of duloxetine for stress urinary incontinence.

Researchers from the Nordic Cochrane Centre, Rigshospitalet, Copenhagen, Denmark, looked at clinical study reports from the European Medicines Agency to assess the benefits and harms of using this drug for stress urinary incontinence. Although they found that duloxetine did lessen the frequency of incontinence, they also observed adverse effects associated with the drug. Harms potentially related to suicidality and violence were 4-5 times more common with duloxetine than with a placebo.

"Given the uncertainty as to whether duloxetine leads to clinically significant improvement in quality of life ... we question the rationale for using <u>duloxetine</u> for stress urinary incontinence," writes Emma



Maund, lead author and researcher at the Nordic Cochrane Centre, with coauthors.

More information: *Canadian Medical Association Journal*, www.cmaj.ca/lookup/doi/10.1503/cmaj.151104

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