

SPINE SAFETY NOTICE:

Updated Prescribing Information for [Cymbalta® \(duloxetine hydrochloride\) Delayed-Release Capsules](#), [Effexor® \(venlafaxine hydrochloride\) Tablets](#) and [Effexor XR® \(venlafaxine hydrochloride\) Extended-Release Capsules](#)

According to MedWatch, FDA notified healthcare professionals of revisions to the WARNINGS and PRECAUTIONS sections of the prescribing information for [Cymbalta® \(duloxetine hydrochloride\) Delayed-Release Capsules](#), [Effexor® \(venlafaxine hydrochloride\) Tablets](#) and [Effexor XR® \(venlafaxine hydrochloride\) Extended-Release Capsules](#). The revised WARNINGS labeling indicates that the development of a potentially life-threatening serotonin syndrome may occur with Cymbalta®, Effexor® or Effexor XR® treatment, particularly with concomitant use of serotonergic drugs (including SSRIs, SNRIs and triptans for Effexor® and Effexor XR®, and triptans for Cymbalta®) and with drugs that impair metabolism of serotonin (including MAOIs). Serotonin syndrome symptoms may include mental status changes (eg, agitation, hallucinations, coma), autonomic instability (eg, tachycardia, labile blood pressure, hyperthermia), neuromuscular aberrations (eg, hyperreflexia, incoordination) and/or gastrointestinal symptoms (eg, nausea, vomiting, diarrhea). The concomitant use of Cymbalta®, Effexor® or Effexor XR® with MAOIs intended to treat depression is contraindicated. If concomitant treatment of Cymbalta® with a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases. If concomitant treatment of Effexor® or Effexor XR® with an SSRI, an SNRI or a 5-hydroxytryptamine receptor agonist (triptan) is clinically warranted, careful observation of the patient is advised, particularly during treatment initiation and dose increases. The concomitant use of Cymbalta® with serotonin precursors (such as tryptophan) or Effexor® or Effexor XR® with serotonin precursors (such as tryptophan supplements) is not recommended.

The revised PRECAUTIONS section for Cymbalta® indicates that patients should be cautioned about the risk of serotonin syndrome with the concomitant use of Cymbalta® and triptans, tramadol or other serotonergic agents. The revised PRECAUTIONS section for Effexor® and Effexor XR® indicates that patients should be cautioned about the risk of serotonin syndrome with concomitant use of Effexor® or Effexor XR® and triptans, tramadol, tryptophan supplements or other serotonergic agents.

The MedWatch 2006 Safety Summary is available at <http://www.fda.gov/medwatch/SAFETY/2006/sep06.htm>

The North American Spine Society is committed to quality patient care through promotion of patient safety and prevention of medical errors. NASS monitors a

variety of government and other resources for patient safety related notices that may be useful to our members. Information from these notices is also archived on the NASS Web site at http://www.spine.org/spine_safety_notices.cfm. This information is provided as a service for information and education only.