

FDA Warns of Suicide Risk for Tramadol

May 26, 2010 — The US Food and Drug Administration (FDA) announced yesterday that it has added a warning of suicide risk to the labels of tramadol hydrochloride (*Ultram*) and tramadol hydrochloride/acetaminophen (*Ultracet*).

The revised labels instruct clinicians not to prescribe tramadol to patients who are suicidal or addiction-prone, and to exercise caution in prescribing the medications to patients who use alcohol excessively, suffer from emotional disturbance or depression, or take tranquilizers or antidepressants.

"Tramadol-related deaths have occurred in patients with previous histories of emotional disturbances or suicidal ideation or attempts as well as histories of misuse of tranquilizers, alcohol, or other [central nervous system–active] drugs," stated letters sent to healthcare professionals by the FDA and PriCara, the maker of the 2 medications and a division of Ortho-McNeil-Janssen Pharmaceuticals.

The letters, 1 for each medication, noted that tramadol, an opioid, can intensify the effects of other opioids as well as alcohol and illicit drugs that depress the central nervous system.

The letters also warned that people with addiction disorders may seek out tramadol and cited the risk of criminal diversion. However, "concerns about abuse, addiction, and diversion should not prevent the proper management of pain," the letters stated.

More information on the FDA announcement is available on the agency's [Web site](#).

To report adverse events related to the 2 pain medications, contact MedWatch by telephone at 1-800-FDA-1088, by fax at 1-800-FDA-0178, online at <http://www.fda.gov/medwatch>, or by mail to 5600 Fishers Lane, Rockville, Maryland 20852-9787.