Ultram (tramadol hydrochloride), Ultracet (tramadol hydrochloride/acetaminophen): Label Change

U.S. Food & Drug Administration

Ortho-McNeil-Janssen and FDA notified healthcare professionals of changes to the Warnings section of the prescribing information for tramadol, a centrally acting synthetic opioid analgesic indicated for the management of moderate to moderately severe chronic pain. The strengthened Warnings information emphasizes the risk of suicide for patients who are addiction-prone, taking tranquilizers or antidepressant drugs and also warns of the risk of overdosage. 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, and other CNS-active drugs. Tramadol may be expected to have additive effects when used in conjunction with alcohol, other opioids or illicit drugs that cause central nervous system depression. Serious potential consequences of overdosage with tramadol are central nervous system depression, respiratory depression and death. Tramadol has mu-opioid agonist activity, can be abused and may be subject to criminal diversion.

[April 2010 - Dear Healthcare Professional Letter [1]: Ultram - Ortho-McNeil-Janssen]
[April 2010 - Dear Healthcare Professional Letter [2]: Ultracet - Ortho-McNeil-Janssen]

SOURCE [3]

Links:
[1] http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM213265.pdf
[2] http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM213266.pdf
[3] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm213264.htm