



The FDA Safety Information and Adverse Event Reporting Program

Tramadol (Ultram) 、 Tramadol/Acetaminophen (Ultracet):

[05/25/2010]

近期美國FDA 發布含Tramadol 藥品之用藥安全資訊，將於仿單加刊警語，說明使用含該成分藥品可能產生自殺之風險，因此該藥品不可使用於具有自殺或成癮傾向者，且應謹慎用於同時使用抗憂鬱藥品或抗精神病藥品、酗酒，以及情緒障礙或憂鬱之患者。此外，該成分藥品使用過量可能造成中樞系統抑制、呼吸抑制或死亡，因此呼籲醫療人員，當處方或調劑該藥品成分時，需注意可能產生濫用或非法使用之情形。

Tramadol (Ultram) 、 Tramadol/Acetaminophen (Ultracet):

Audience: Pain management healthcare professionals

[Posted 05/25/2010]

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 overdose. 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 overdose 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.