



Tramacet® and Abuse Potential

Tramacet® (tramadol 37.5mg/acetaminophen 325mg) has recently been approved and marketed in Canada for the acute (up to five days) treatment of moderate to severe pain. Tramadol has affinity for the mu-opioid receptors, though its affinity is much less than that of morphine and even codeine.¹ It also weakly inhibits serotonin and norepinephrine re-uptake,² which makes the drug a target for more drug interactions. Despite its opioid-like properties, it has been touted as a drug with low potential for abuse. Tramacet® is regulated as Schedule F in Canada.

Tramadol has been available in other countries since 1977 and is now marketed in more than 100 countries worldwide. The World Health Organization (WHO) has not designated it for international control, but rather drug surveillance.³ Abuse rates are variable in European countries⁴, though an analysis of abuse in Europe suggested that tramadol has a very low incidence of abuse compared to most other drugs of abuse.³

The Federal Drug Administration (FDA) approved tramadol in 1995. The FDA set up a special committee to monitor the abuse of tramadol after its approval. A proviso of tramadol's approval was that if any of the information gathered suggested tramadol did have potential for abuse, that the drug would be scheduled (in the US, "scheduled drugs" refers to drugs with at least some potential for abuse). To date, scheduling has not been recommended.⁴

The rate of abuse after the first year of tramadol's availability in the US was determined to be 2 to 3 cases/100 000 patients treated.³ The rate declined to 1 case/100 000 patients treated in the subsequent year. How does this compare with other opioids and drugs of abuse? This is difficult to ascertain. Certainly there is a higher rate of reporting adverse drug reactions in the first few years of a drug's availability.⁴ Also, there is not enough data in the reports to determine if all were true cases of abuse. However, there have been some comparisons. The Drug Abuse Warning Network in the US reports rates of abuse of 1.46% with tramadol; 1.55% with codeine; and 1.86% with propoxyphene.⁵ On the other hand, data from Germany suggests tramadol has a lower abuse potential than buprenorphine or pentazocine.³

Abuse of tramadol has been reported worldwide. While abuse has been reported in those with no history of substance abuse,^{4,6} 97% of reported cases of tramadol abuse occurred in patients with a history of substance abuse.⁴ Janssen-Ortho has defined a "Risk Management Strategy" for marketing purposes to help reduce abuse of tramadol.⁷ This strategy can be found in the Tramacet® product monograph.

There does not seem to be a clear consensus as to the abuse potential of tramadol. Until further information is available, it is prudent to avoid the use of tramadol in patients with a history of substance abuse. For patients prescribed tramadol, usage should be monitored (i.e. via prescription use) with the same discretion as other opioids and drugs of abuse.

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In terms of efficacy for acute pain, tramadol has been shown to be more effective than placebo and the combination of tramadol/acetaminophen has been shown to be more effective than tramadol alone.⁸ Most studies have found tramadol/acetaminophen to exhibit similar or less efficacy (not greater) in comparison with acetaminophen/other opioids (codeine, hydrocodone) as well as ibuprofen.⁹ Tramadol/acetaminophen offers no advantage to standard analgesics⁸ and is more costly. A very specific indication that has been proposed is in patients after surgery of the thorax or upper abdomen who have a risk of poor cardiopulmonary function and when non-opioid analgesics are contraindicated.^{9,10}

If you have any questions or would like more information on this topic, please call the Saskatchewan Drug Information Service

1-800-667-3425 (Saskatchewan), 966-6340 (Saskatoon)

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References available on the SDIS website or by request.

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