



CUBIC HEALTH INC.

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DURAGESIC LINKED WITH RESPIRATORY DISTRESS IN ADOLESCENTS

WINNIPEG, October 29th, 2004 – Health Canada has received two case reports of death suspected of being associated with the use of Duragesic® (transdermal fentanyl system) prescribed off-label to adolescents. Off-label prescribing refers to the use of a medication for conditions or situations which are not approved by federal regulatory authorities. Fentanyl is a potent narcotic that is used most commonly in treating chronic pain in patients requiring continuous opioid analgesia for pain that is not well managed with weaker or short-acting opioids.

The drug was being used off-label in these two cases because it is contraindicated for the management of acute or post-operative pain, for mild or intermittent pain, and in opioid-naïve patients. Furthermore, the use of Duragesic® in children under 18 years of age is not recommended in Canada.

In one case, a 15 year-old girl was prescribed Duragesic® 25 for chronic headache. She was discovered unresponsive with respiratory depression 21 hours after her first and only application of the Duragesic® patch. She was resuscitated, but suffered severe brain damage and died two days later. In the other case, a 14 year-old boy was prescribed Duragesic® 25 for throat pain due to infectious mononucleosis (commonly known as mono). He was found in respiratory distress 14 hours after the first and only patch had been applied. Resuscitative efforts were unsuccessful.

An understanding of how the Duragesic® patch works is key to the safe prescribing and use of the product. When the patch is applied initially, a loading dose of the drug is delivered via the silicone-based contact adhesive. The fentanyl drug reservoir in the patch is located behind a rate controlling membrane. A fentanyl depot accumulates in the upper skin layers, diffuses to the dermis, and is then available for uptake into the systemic blood circulation. Maximum blood levels of the drug normally occur 12 to 48 hours after application. When the Duragesic® patch is removed, fentanyl continues to be absorbed into the blood stream from the depot in the upper skin layers.