RADARS® SYSTEM

Title:	**Buprenorphine/Naloxone Pediatric Ingestion: Exposure Rates Differ Between Film and Tablet Formulations**
Authors:	Lavonas EJ, Martinez EH, Severtson SG, Dart RC, Green JL
Meeting:	ASAM
Date:	April 2014
Location	Orlando, FL

Abstract:

Background: Buprenorphine ingestion can cause life-threatening poisoning in young children. Previous reports have found that film formulations are associated with lower pediatric exposure rates than tablet formulations.

Aim/Hypothesis: The purpose of this study is to determine whether these relationships are stable over time.

Methods: Data from Researched Abuse, Diversion, and Addiction-Related Surveillance (RADARS®) System Poison Center Program, January 2011 – March 2013, involving unintentional exposure to buprenorphine sublingual tablets or film by children aged < 6 years were analyzed. To adjust for medication availability, event ratios (rates) were based on the number of patients filling prescriptions for each formulation ("Unique Recipients of a Dispensed Drug", URDD). Negative binomial regression was used to produce quarterly rates, average rates, and 95% confidence intervals (CIs).

Results: 1,695 reports were analyzed. Exposure rates for buprenorphine/naloxone combination tablets (7.0 exposures per 10,000 URDD (CI: 6.6 – 7.3)) exceeded those for buprenorphine monoingredient tablets (2.8 (CI: 2.4 – 3.2)) and combination film (0.9 (CI: 0.8 – 1.0)). The combination tablet and monoingredient tablet rates were significantly greater than film rates (Rate Ratios (RR): 7.6 (CI: 6.7 – 8.6; $p<0.0001$) for combination tablets and RR: 3.1 (CI: 2.6 – 3.7; $p<0.0001$) for monoingredient tablets compared with film, $p<0.0001$ for each). Relationships were consistent over time except for slight decreases in the monoingredient tablet rate.

Discussion: This study cannot determine whether the differences are caused by packaging or formulation. This analysis did not include generic buprenorphine/naloxone tablets, introduced in February 2013.

Conclusion: The rate of unintentional exposures to buprenorphine/naloxone sublingual film by young children is significantly less than the rate of exposure to buprenorphine/naloxone or buprenorphine monoingredient tablets.

Supported by: Reckitt-Benckiser Pharmaceuticals