

## **Morphine Sulfate Oral Solution 100 mg per 5 mL (20 mg/mL): Medication Use Error - Reports of Accidental Overdose**

U.S. Food & Drug Administration

**AUDIENCE:** Pharmacy, Oncology, Pain Management

**ISSUE:** Roxane Laboratories and FDA notified healthcare professionals of serious adverse events and deaths resulting from accidental overdose of morphine sulfate oral solutions, especially when using the high potency 100 mg/5mL product. In most of these cases, morphine sulfate oral solutions ordered in milligrams (mg) were mistakenly interchanged for milliliters (mL) of the product. The approval of this product is part of FDA's unapproved drugs initiative. Prior to the recent approval, Roxane marketed a morphine sulfate oral solution with the strength expressed as 20 mg/mL, using a container label and carton labeling that had brown lettering on a white background. The newly approved product labeling and packaging feature revisions intended to reduce the risk of medication errors.

**BACKGROUND:** Morphine Sulfate Oral Solution 100 mg per 5 mL (20 mg/mL) is indicated for relief of moderate to severe acute and chronic pain in opioid-tolerant patients.

**RECOMMENDATION:** See Roxane's "Dear Healthcare Professional Letter" for a complete description and photos of labeling and product packaging changes. Changes include:

- A warning stating "ONLY FOR USE IN PATIENTS WHO ARE OPIOID TOLERANT" is displayed in a box to highlight that the morphine sulfate oral solution 100 mg per 5 mL (20 mg/mL) is indicated for use in opioid-tolerant patients only. The 100 mg per 5 mL concentration of morphine sulfate may cause fatal respiratory depression when administered to patients not previously exposed to opioids.
- The strength is presented as 100 mg per 5 mL followed by a less prominently displayed concentration of (20 mg/mL). The intent of this designation is to help differentiate this product from the 20 mg/5 mL morphine sulfate product.
- A bright yellow background is used on multiple sides of this product to differentiate the morphine sulfate oral solution 100 mg per 5 mL (20 mg/mL) from other morphine sulfate oral solutions marketed by Roxane with a white background.
- The drug name, strength and concentration are displayed in white lettering on a red background as an additional means of differentiating this product from other concentrations of morphine sulfate oral solutions.
- A reminder is presented to the pharmacist to dispense the product to each

patient with the enclosed Medication Guide.

- Both the 30 mL and 120 mL bottles of morphine sulfate 100 mg per 5 mL (20 mg/mL) oral solution are packaged with a calibrated oral syringe to provide accurate dose measurements. Healthcare providers should read the instructions in the Medication Guide that describe the correct use of the oral syringe in order to help prevent medication errors from occurring.
- Healthcare providers should discuss the correct use of the oral syringe with their patients.

[December 2010 - [Dear Healthcare Professional Letter](#) [1] - Roxane Laboratories]

[January 2010 - [Prescribing Information, Morphine Sulfate Oral Solution](#) [2] - Roxane Laboratories]

[January 2010 - [Medication Guide, Morphine Sulfate Oral Solution](#) [3] - Roxane Laboratories]

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**Links:**

[1] <http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM239561.pdf>

[2] [http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2010/022195s002lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2010/022195s002lbl.pdf)

[3] <http://www.fda.gov/downloads/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/UCM239632.pdf>

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