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ISMP Applauds New Look for Oral Morphine Solution

Revised packaging heeds Institute and FDA's call to prevent errors

Horsham, Pa---In January 2010, the Food and Drug Administration (FDA) approved the first morphine sulfate oral 20 mg/mL solution since launch of the agency's initiative to ensure all marketed drug formulations have FDA approval. The new product labeling and packaging features revisions long advocated by ISMP to reduce the risk of confusion between the different strengths of oral morphine solutions.

Roxane previously marketed an unapproved morphine sulfate oral solution with the strength expressed as 20 mg/mL and container and carton labeling with brown text on a white background that was very similar to other FDA-approved Roxane products, including other morphine solution strengths. FDA and ISMP received reports of medication errors involving labeling of unapproved morphine sulfate oral solutions 20 mg/mL that resulted in accidental overdoses and deaths.

In the newly approved product, the strength is presented as 100 mg per 5 mL followed by a less prominently displayed concentration of 20 mg/mL. A bright yellow background is used on multiple sides of the product, and drug name and strength are displayed in white lettering on a red background to differentiate it from lower strength morphine oral solution labeling. The carton and container label also warns that the drug should only be used in patients who are opioid tolerant and reminds pharmacists to dispense the product with the enclosed Medication Guide.

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The new prescribing information includes a boxed warning about the risk of medication errors due to confusion over the various concentrations and "mg" versus "mL". The warning is also mentioned in the indications and usage, dosage and administration, and warnings and precautions sections.

Unapproved morphine sulfate oral solution 20 mg/mL may still be available from other drug manufacturers. In general, when a manufacturer obtains approval for a previously unapproved product, the FDA allows a grace period for transition. Firms marketing unapproved morphine sulfate oral solution 20 mg/mL have been given 180 days after the date of first approval to stop shipment in interstate commerce.

For more details on changes in the newly approved oral morphine solution labeling and packaging, see the cover story of the most recent issue of *the ISMP Medication Safety Alert!* newsletter at: http://www.ismp.org/Newsletters/acutecare/articles/20100211.asp

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