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October 22, 2003

Dear Healthcare Professional:

Elan issued a Dear Healthcare Professional letter, dated June 13, 2003, for Roxanol™ products. That letter contained the following statement, “*Prescribers and dispensers should be aware that these and other concentrations of morphine sulfate are available from various manufacturers with the concentration expressed in mg/tablespoon (5 mL).*” Elan is reissuing the letter with the following revision to this statement: “*...expressed in mg/~~tablespoon~~ teaspoon (5 mL).*”

Please note that the instructions on how to clearly prescribe the medication remain unchanged, as noted below:

Serious adverse events and deaths have resulted from accidental overdose of high concentration morphine sulfate oral solutions. In most of these cases, morphine oral solutions ordered in *milligrams (mg)* were mistakenly interchanged for *milliliters (mL)* of the product, resulting in 20-fold overdoses. For example, a prescribed dose of *5 mg* was mistakenly administered as *5 mL* (100 mg) of the morphine sulfate concentrated solution.

Élan Pharmaceuticals currently distributes three concentrated morphine sulfate oral solutions:

- Roxanol™ CII (morphine sulfate) Concentrated Oral Solution (20 mg/mL); available in 30 mL and 120 mL bottles with calibrated dropper
- Roxanol™-T CII (morphine sulfate) Concentrated Oral Solution (20 mg/mL)-Tinted, Flavored; available in 30 mL and 120 mL bottles with calibrated dropper
- Roxanol 100™ CII (morphine sulfate) Concentrated Oral Solution (20 mg/mL); available in a 240 mL bottle with calibrated patient spoon

Prescribers and dispensers should be aware that these and other concentrations of morphine sulfate are available from various manufacturers with the concentration expressed in mg/teaspoon (5 mL).

To assure that your patient receives the proper dose of morphine sulfate oral solution, please write a prescription for morphine sulfate oral solution clearly by including the following:

(1) the concentration of morphine sulfate oral solution to be dispensed AND (2) the intended dose of morphine in milligrams (mg) with the corresponding volume in milliliters (mL or cc) written out in the directions.

To demonstrate, a dose of 15 mg of morphine oral solution should be written as:

Roxanol 20 mg/mL

Sig: 15 mg (0.75 mL or cc) q 4 hours prn.

Dispense: 30 mL

Roxanol 20 mg/mL

Sig: 15 mg (0.75 mL or cc) q 4 hours prn.

Dispense: 120 mL

Roxanol 100™ - (20 mg/mL)

Sig: 15 mg (0.75 mL or cc) q 4 hours prn.

Dispense: 240 mL

It is important that the prescription is filled with the proper concentration of morphine sulfate oral solution to prevent potential medication errors. If the specified morphine sulfate oral solution is unavailable, please contact the prescriber.

We hope you find this letter helpful in clarifying the importance of proper ordering and dispensing of morphine sulfate oral solution in order to prevent medication errors. If you have any further questions or would like additional information, please contact our Medical Information Services Department at 1-888-638-7605.

Sincerely,

A handwritten signature in black ink, appearing to read 'C. O'Brien', with a long horizontal flourish extending to the right.

Chris O'Brien, M.D.
Sr. Vice President, Medical Affairs