



Nurse Advise-ERR®

Educating the healthcare community about safe medication practices

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Safe practice with the potent once daily opioid **EXALGO**

On March 1, 2010, FDA approved the Schedule II controlled substance **EXALGO**, a once daily **HYDRO**morphone hydrochloride extended-release tablet. Exalgo is indicated for the management of moderate to severe pain in opioid-tolerant patients who require continuous, around-the-clock opioid analgesia for an extended period of time. The drug is not indicated for use as an “as needed” (PRN) analgesic or for the management of acute or post-operative pain. Exalgo is available in 8, 12, and 16 mg tablet strengths that should be swallowed whole and not broken, chewed, dissolved, crushed, or injected, as this will cause immediate release of the drug which could lead to an overdose. Exalgo is contraindicated in patients who are not opioid-tolerant or those with impaired pulmonary function, paralytic ileus, or a narrowed or obstructed gastrointestinal (GI) tract because it can slow respirations and GI tract motility.

Exalgo has been launched with a Risk Evaluation and Mitigation Strategy (REMS) program, which includes a Medication Guide and educational materials to ensure appropriate patient selection and dosing. The product packaging contains an encased statement **For opioid-tolerant patients only** to emphasize this point. Patients are considered opioid-tolerant if they have been taking at least one of the following opioids for 1 week or longer:

- 8 mg oral **HYDRO**morphone/day
- 25 mg oral oxymorphone/day
- 30 mg oral oxy**CODONE**/day
- 60 mg oral morphine/day
- 25 mcg transdermal fenta**NYL**/hour
- Equianalgesic dose of another opioid.

The product package also highlights the words “Once Daily” to remind dispensing pharmacists of the dosing frequency for this medication.

Dose conversion to Exalgo requires calculation. Guidance is provided in the prescribing information to help ensure safe conversion from other opioids to Exalgo. The starting dose for Exalgo depends on the specific dose of opioid the patient is taking and the calculated total daily dose of oral **HYDRO**morphone. Prescribers should refer to the full prescribing information for dosage and instructions for administration.

Physicians may prescribe Exalgo 8 mg tablets as an initial daily dose. The 8 mg strength of Exalgo overlaps with currently marketed **HYDRO**morphone immediate-release products. This overlap in strength may contribute to medication errors if inadvertent substitution between the two **HYDRO**morphone products occurs. Confusion between the immediate- and extended-release products could result in an overdose, which may lead to serious adverse events such as respiratory depression and death. Confusion between immediate- and extended-release products could also result in an underdose, leading to poor efficacy. To prevent mix-ups and other types of medication errors with Exalgo, consider the safety recommendations provided below.

Prescribers

- Review the patient’s medication history and verify that the patient is opioid-tolerant before prescribing Exalgo.
- To help minimize the risk of confusion between **HYDRO**morphone

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safetywires

⚡ LOVENOX unit dose syringe alert. ISMP recently posted a **Special Alert** about the manufacturer’s label coming loose from certain Lovenox (enoxaparin) unit dose syringes, a problem identified by several hospitals. In one case, a needlestick injury resulted when a nurse’s glove stuck to the label adhesive as she was withdrawing the syringe from the patient and before the protective needle sheath could be engaged. For more information about the alert, please visit: www.ismp.org/sc?k=lovenox.

⚡ Generic enoxaparin syringe issue. Sandoz, the manufacturer that released a generic enoxaparin earlier this month, confirmed a different problem (see above *safetywire* on **LOVENOX**) with some of its prefilled syringes: premature activation of a spring that pushes a safety shield over the needle before removal from the package, making it impossible to inject the drug (Figures 1 and 2). Sandoz told us on Tuesday that the company is aware of



Figure 1. Syringe with spring spontaneously activated prematurely and with safety shield locked over the needle prior to use.



Figure 2. Unaffected syringe.

the problem and is working to resolve the situation. The company advises pharmacists to call Sandoz for more information (1-609-627-8500). Defective syringes may be returned for credit.

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products, include the proprietary (brand) name Exalgo on prescriptions, which may provide greater differentiation than simply using the established (generic) name alone.

■ If the established (generic) name is included or used alone, spell out “HYDROmorphone extended-release” instead of “HYDROmorphone ER.” Pharmacists may overlook the modifier “ER” and dispense HYDROmorphone immediate-release tablets instead of the extended-release tablets, resulting in inadequate around-the-clock pain control.

■ When prescribing the immediate release HYDROmorphone product by the established (generic) name, include just “HYDROmorphone.” Do not attach modifiers such as “IR” for immediate-release. Pharmacists may misinterpret “IR” for “ER,” especially with handwritten orders, and dispense Exalgo in error, resulting in dispensing the wrong formulation and increasing the potential for patient harm.

Pharmacists and Nurses

■ Verify the prescribed HYDROmorphone product with the order or prescription. Exalgo is dosed once daily while the usual dosing frequency for immediate-release HYDROmorphone is every 4 to 6 hours as needed.

■ Verify opioid tolerance by asking the patient for his/her medication history and checking the patient’s pharmacy

profile and medication administration record. Build alerts into the pharmacy computer system to remind the pharmacist to verify opioid tolerance.

■ Counsel patients and their caregivers to take Exalgo once daily, to swallow the tablets whole without chewing or crushing them, and to avoid alcohol while taking this medication. Also advise patients to inform their healthcare provider if Exalgo does not provide adequate pain control.

■ Verify patient understanding about how to take the tablets at home by asking open-ended questions.

■ Advise patients to read the Medication Guide (provided with the outpatient prescription) and call their healthcare provider if they have any questions.

■ Instruct patients to check the appearance of each Exalgo tablet before taking it to ensure it matches the product description or image when this information is provided on the pharmacy-generated label or in the pharmacy leaflet.

This article was provided by the FDA Office of Surveillance and Epidemiology, Division of Medication Error Prevention and Analysis, in cooperation with ISMP.

Editor’s note: ISMP urges clinicians to ensure Exalgo is prescribed, dispensed, and administered only to opioid-tolerant patients with chronic pain, not acute pain.

► Special Announcements

Medication safety blog. ISMP president Michael Cohen contributes a guest blog on *Philly.com*, the Web site operated by the *Philadelphia Inquirer* and *Philadelphia Daily News*. Be sure to read the blog regularly and add comments about your experiences to enhance the medication safety-related postings for healthcare consumers. The blog pages’ link is: www.philly.com/philly/health_and_science/97905324.html.

Nursing Leadership webinar. Based on the 2009 Nursing Leadership Congress proceedings, the final webinar in the series of four **free** webinars will be presented on **August 26: Health Information Exchange for Promoting Patient Safety**. Learn how one hospital system is meeting the challenge of providing a connected care experience for patients who have clinical data in disparate ambulatory and acute care electronic medical records. For more information about the webinar and to register, please visit: <http://nursingleadershipcongress.com/Webinars.asp>.

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⚡ Questionable safety with continuous inhalation albuterol infusion set-up.

Some facilities have pharmacy staff add albuterol inhalation solution to an IV bag; the solution is intended for respiratory therapy to use with an infusion pump for continuous administration into a nebulizer and face mask for patients with status asthmaticus. In order to use this mixture with an infusion pump, the IV bag is spiked with IV tubing, and the distal end of the tubing is cut off just above the Luer connector. This allows the end of the tubing to be jury-rigged so it connects to the nebulizer, which is attached to a face mask (Figure 1). One concern with placing the drug in an IV bag is the risk of accidental



Figure 1. Cut end of the IV tubing was inserted into the reservoir of nebulizer to supply continuous albuterol for nebulization. The nebulizer was connected to the gas source (air or oxygen) from a wall outlet or tank. The “Y” injection port invites errors.

IV infusion of the bag contents. But another concern has also surfaced. Recently, a nurse discovered that a patient’s IV methylPREDNISolone and famotidine were being infused into the “Y” port on the IV tubing that was connected to the nebulized albuterol rather than the intended IV line. As a result, this patient did not receive his systemic steroid or H₂ antagonist, and he likely received diluted albuterol when these medications ran through the tubing connected to the nebulizer. After identifying the error, the patient’s treatment was changed to oral corticosteroids and intermittent albuterol via the nebulizer—where the medication is added directly to the nebulizer cup prior to each treatment. His condition improved once he

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Neuromuscular blocker *mix-up* in the pharmacy

An error was reported at a hospital in which minibags had been accidentally prepared with vecuronium instead of valproate sodium injection. Two minibags were initially prepared to cover the 12-hour dosing interval. Both medication vials had been close to one another in the pharmacy, had red caps, and were approximately the same size. Fortunately, after the first infusion began, the patient was able to press the call bell for assistance when it became difficult to breathe. The nurse stopped the infusion and transferred the patient to the ICU for monitoring.

Initially, the event was attributed to the patient's preexisting neurological symptoms. Also, pain medication had just been administered, which staff thought contributed to the patient's difficulty with breathing. Since the patient was able to move her arm to use the call button, staff didn't suspect that a paralytic agent had been given in error. The next day when the second minibag—also vecuronium labeled as valproate sodium—was started, the same symptoms occurred. A short time later, a pharmacist called the unit to report that an error had been discovered. After gathering vials to prepare the next doses, a technician had noticed they were different than the vials previously used.


Pharmacy has now separated the products, moving the vecuronium to a restricted access area, and removed unnecessary vials of vecuronium outside the pharmacy. They also started a new process whereby materials for each preparation are placed in a separate bin to organize the checking process.

To help reduce errors with neuromuscular blockers, The United States Pharmacopeia (USP) requires warnings on the cap and ferrule of the vial stating the drug is a paralyzing agent. Neuromuscular blockers should always be sequestered in a secure, lidded bin (or a separate, lidded automated dispensing cabinet [ADC] compartment) labeled "Paralytic Agent," and stored away from other drugs, in both the pharmacy and in limited clinical areas (e.g., ED, PACU, ICU). Specialty bins for storage of these agents are also available commercially (to view an example, visit: <http://shop.healthcarelogistics.com/default.aspx?page=item+detail&itemcode=17354>).

For added safety, some hospitals apply ShrinkSafe (http://shrinksafe.com/products_idband.asp) to the vials upon receipt in the pharmacy. This is a sleeve that fits over vials and allows visibility of the drug name through a clear panel. It adds vivid warnings about the drug's paralytic nature and also forces the user to remove the cover, which increases the chance the "paralytic" warning will be recognized. Because it may take more time to open these vials, some hospitals have opted to leave the sleeves off succinylcholine used in kits for rapid sequence intubation while still applying the sleeves to other neuromuscular blocker vials. However, keep in mind that using ShrinkSafe wrap on vials of multiple neuromuscular blocker agents can make them look similar and contribute to mix-ups among the various agents. Thus, minimizing the variety of neuromuscular blocker agents stored in the pharmacy and clinical areas will help reduce similarity in appearance (with or without the sleeves).

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began receiving his medications as intended. The hospital has recently changed its delivery method and is now adding albuterol inhalation solution directly into a nebulizer cup, instead of employing the more risky continuous infusion from an IV bag.

 **Lot number documentation helps detect vaccine errors.** A nurse working in an immunization clinic was involved in a medication error. She had a client who needed an adult hepatitis B vaccine. The nurse removed the vial from its carton, read the vial label, and proceeded to draw up the vaccine to be administered. Only when she was doing data entry after administration did she realize she had given an adult hepatitis A vaccine. She noticed the error based on the lot number, which was different than previously documented hepatitis B lot numbers. The clinic stocks GlaxoSmith-Kline adult hepatitis B vaccine and Merck adult hepatitis A vaccine. Both vials have orange caps/covers, which may have contributed to the mix-up. Another nurse apparently removed a vial of hepatitis A vaccine from the manufacturer's carton, and then not needing it, put it in an empty hepatitis B vaccine carton. The nurse later realized the label stated "hepatitis A" but she had read "hepatitis B" because that was what she was expecting it to be (confirmation bias). Replacing a vial of medicine into the wrong carton is a problem we previously mentioned in our acute care newsletter with insulin (www.ismp.org/Newsletters/acute/updates/20080508-1.asp). If possible, consider removing vials from their cartons prior to storage. Also, document the vaccine, including the manufacturer and lot number, on the vaccine form/log just prior to administration (but do not document actual drug administration on the medication administration record [MAR] until after the vaccine has been given). Recognizing a major difference in lot number format from what is normally recorded could help in recognizing that the wrong product is in hand. Involving a family member to assist in the double-check process is also advisable.

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Report medication errors to ISMP at 1-800-FAIL-SAF(E).