


ISMP Medication Safety Alert!®

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Safety Briefs

 **Near sight/sound dead hit!** **OMACOR** (omega-3-acid ethyl esters), a new drug distributed by Reliant Pharmaceuticals, is indicated as an adjunct to diet to reduce very high triglyceride levels (500 mg/dL or more) in adult patients. The drug is also being studied as adjuvant therapy for prevention of further heart attacks in patients who have already survived at least one. It's available in 1 g capsules, and the recommended dose is 4 g (4 capsules) daily or 2 g BID. Prescriptions for Omacor have just begun to arrive in pharmacies, but we've already heard about a name-related safety issue. A pharmacist reported an error in which a telephone order for Omacor 1 g BID was misheard as **AMICAR** (aminocaproic acid) 1 g BID. Fortunately, the patient read the drug information sheet before taking the medication and called the pharmacy to let the pharmacist know he was expecting a drug that reduced his triglyceride levels. An actual mix-up might place certain patients at risk. Amicar, an antifibrinolytic agent available for many years, is used to enhance hemostasis when fibrinolysis contributes to bleeding. Both Amicar and Omacor are available in a 1 g oral dosage strength. For use in acute bleeding due to elevated fibrinolytic activity, Amicar is given in higher oral doses than Omacor, but confusion could still occur. In most settings, Amicar isn't used often so pharmacists and nurses may not realize the labeled dose is 5 g orally during the first hour of treatment, followed by a continuing dose of 1 g/hour. The drug is also available for IV use. If patients receive Amicar instead of Omacor, the risk of thrombosis would be increased, as would a host of adverse reactions associated with the drug. The substitution of Omacor for patients that truly need Amicar may be even more significant, potentially leading to serious bleeding conditions. We believe that name similarity is so striking when handwritten or pronounced, and the potential for serious errors so high, that ***the product name, Omacor, should be changed.*** Meanwhile, set an alert

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Propofol sedation: Who should administer?

PROBLEM: Using propofol (DIPRIVAN) to sedate patients during endoscopic and other diagnostic procedures is gaining momentum in a growing number of hospitals, outpatient surgery centers, and physician offices.¹ In trained hands, propofol offers many advantages over other drugs used for sedation because it:

- Has a rapid onset (about 40 seconds) and a short duration of action
- Allows patients to wake up, recover, and return to baseline activities and diet sooner than some other sedation agents
- Reduces the need for opioids, thus resulting in less nausea and vomiting.²

Trained nurses in most critical care settings often administer propofol safely to patients who are intubated and ventilated. However, some practitioners have been lulled into a false sense of security, allowing the drug's good safety profile to influence their beliefs that propofol is safer than it really is. In untrained hands, propofol can be dangerous, even deadly; administration to a nonventilated patient by a practitioner who is not trained in the use of drugs that can cause deep sedation and general anesthesia is not safe, even if the drug is given under the direct supervision of the physician performing the procedure.² After all, how much supervision can the physician provide if he or she is focused on the procedure itself? Not enough, as the following events show.

Believing that propofol was "used all the time in ICU," a gastroenterologist asked a nurse to prepare "10 mL" (10 mg/mL) of the drug for a patient undergoing endoscopy in his room. The nurse obtained the drug from an automated dispensing cabinet via override before she transcribed the order to the patient's record. Another nurse who was trained in the use of moderate sedation,

but not deep sedation or anesthesia, assisted the gastroenterologist. After questioning the physician about the dose (100 mg is a high dose), she began administering the propofol via an infusion pump. The patient suddenly experienced respiratory arrest. Fortunately, ICU staff were able to help with the emergency and quickly intubated and ventilated the patient.

Another case involved a physician who thought he could safely administer propofol himself while performing a breast augmentation. Unfortunately, his patient, a young woman, died of hypoxic encephalopathy because he failed to notice the patient's rapidly declining respiratory status, as had his surgical assistant, who was not qualified to monitor patients under deep sedation or anesthesia.³

Nurses have also been asked to administer "a little more" propofol if the patient moved after the anesthesiologist left the room. In these cases, the anesthesiologist would leave the propofol syringe and needle in the IV port after placing the block and leave the nurses in the room to monitor the patient alone. Initially, the nurses reluctantly complied. Later, they brought the issue to the attention of hospital leaders, citing that they were worried about the safety of this practice.²

There are several compelling reasons why all healthcare providers should be worried about nurse-administered propofol.

Strict product labeling. AstraZeneca, the manufacturer of Diprivan, states in its product labeling that the drug is intended for general anesthesia or monitored anesthesia care sedation, and that the drug should be administered only by persons trained in the administration of general anesthesia and not involved in the surgical/diagnostic procedure. (For sedation of intubated, mechanically ventilated adult patients in the ICU, product

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in the order entry computer system, match the drug's indication to the patient's diagnosis before dispensing either of these drugs, and consider using tall man letters when expressing the drugs (e.g., **OMacOR** and **AMicAR**) if both medications are available in inventory.

**Seeing (and hearing) double.**

A nurse reported several incidents of pressing a number key on **Alaris SE pumps** (formerly **Signature Edition GOLD Infusion System**) and getting an unintended repeat of that number. For example, if they pressed "5," it registered "55" on the screen. Recently, when programming an infusion for 36 mL per hour, the pump registered 366 and it wasn't noticed, leading to overinfusion. According to the nurse and a biomedical engineer at the facility, the operator will also hear two beeps instead of one if the number is repeated. This can occur when setting the rate or while in the drug calculation mode, but in all cases, the actual rate will be higher than intended. The facility has had 11 such events since April 2003. The medications involved were high-alert drugs such as TPN, oxytocin, insulin, and magnesium sulfate. People may look at the keys, not the screen, when pressing the numbers. Just like a cell phone, if you do not confirm the numbers before you press "send," the result may not be as expected. Being alert to the sound of an extra beep can help prevent overinfusions, as can following a habit of never starting an infusion without first reviewing and confirming the numbers on the screen. Upon initiation, bag changes, and other regular intervals, staff should also require an independent double check of all pump settings for neonatal infusions and high-alert drug infusions. The Alaris SE pump has an option to employ **Guardrails** software to alarm when rate, volume, or dose limits have been breached (as appropriate for different patient populations or patient care areas). This feature will help prevent serious overinfusions if the erroneous infusion rate exceeds safe limits. Incidentally, the problem with double entries was reproduced in a laboratory setting, but only with special manipulation of the keys. We contacted Alaris and ECRI about the problem. Since then, one additional facility has reported a similar error with an Alaris pump. We'd be interested in hearing from you if you have encountered this type of event with any brand infusion pump. Please notify us at ismpinfo@ismp.org.

Propofol continued

labeling notes that the drug should be administered only by persons skilled in the management of critically ill patients and trained in cardiovascular resuscitation and airway management.)

Unpredictable and profound effects.

Propofol dosing and titration is variable, based on the patient's tolerance to the drug. Profound changes can occur rapidly. A patient can go from breathing normally to a full respiratory arrest in seconds, even at low doses, without warning from typical assessment parameters.²

No reversal agent. Unlike other sedation agents (e.g., midazolam, morphine), there is no reversal agent for propofol. Adverse effects must be treated until the drug is metabolized.

Financial incentives. Unwillingness of insurers to reimburse anesthesia care for some procedures such as diagnostic endoscopy has increased the use of nurse-administered propofol.^{1,2} Untrained nurses may be caught in the middle of the debate and feel pressured to administer propofol.²

Legal barriers. Nurse-administered propofol falls under each state's Nurse Practice Act. More than a dozen states specifically consider this function beyond the scope of nursing practice.²

SAFE PRACTICE RECOMMENDATION: At each organization, an interdisciplinary team, including chair of the anesthesia department, should establish policies and practice guidelines for the administration of propofol (or other induction agents such as thiopental, methohexital, or etomidate) to nonventilated patients undergoing surgical or diagnostic procedures. To best inform your team's decision about this controversial issue, consider the following:

Review regulations/position statements.

Check with your State Board of Nursing to determine if nurse-administered propofol is deemed within the professional nurses' scope of practice. If so, explore the various position statements available on this topic from professional societies, including the:

- [American Society of Anesthesiologists \(ASA\)](#)
- [American Association of Nurse Anesthetists \(AANA\)](#)
- [American Association for Accreditation of Ambulatory Surgery Facilities \(AAAASF\)](#)
- [American College of Gastroenterology \(ACG\)](#)
- [American Gastroenterological Association \(AGA\)](#)
- [American Society for Gastrointestinal Endoscopy \(ASGE\)](#)
- [Society of Gastroenterology Nurses and Associates \(SGNA\)](#)

In brief, the ASA, AANA, and AAAASF believe that only persons trained in the administration of general anesthesia, who are not simultaneously involved in the procedures, should administer propofol to nonventilated patients. The ASA also suggests that, if this is not possible, non-anesthesia staff who administer propofol should be qualified to rescue patients whose level of sedation becomes deeper than intended, and who enter, if briefly, a state of general anesthesia. The ACG, AGA, ASGE, and SGNA endorse nurse-administered propofol under the direction of a physician if state regulations allow it, and if the nurse is trained in the use of drugs causing deep sedation and capable of rescuing patients from general anesthesia or severe respiratory depression.

Define policies. Based on patient safety, professional association position statements, and applicable state laws, determine the qualifications of professionals who can administer propofol to nonventilated patients during procedures. If nurse-administered propofol is acceptable, specify the circumstances and required education and mentorship that must be accomplished beforehand, and competencies that must be evaluated and met periodically (ACLS certification alone is not sufficient²). Decide if the location of propofol administration plays a factor. Location need not be limited if criteria are met, including expertise to intubate patients, which is difficult to meet in physician office settings.¹ Define the intended level of sedation. However, even if moderate sedation is intended, all patients given propofol should receive care consistent with deep sedation.

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Special Announcements...

New video with free viewing.

A new patient safety video produced by FDA in cooperation with ISMP, *Avoiding Fatal Overdoses with Fentanyl Patches*, is now available at: www.ismp.org/Pages/FDAVideos.htm. The video, which can be downloaded for free viewing, covers various ways in which fentanyl patches have been involved in serious errors and how to avoid them.

ISMP conference. Join ISMP and Joint Commission Resources on November 14, 2005, for a 1-day conference, *Medication Reconciliation: An Organizational Approach to Improving Patient Safety Outcomes*, to be held in Oakbrook Terrace, IL. The program will cover the Joint Commission's expectation for medication reconciliation in hospitals and the role of technology in this process. For details, visit: www.jcinc.com/education.asp?durki=10078&site=5&return=8386.

ISMP exhibitor theaters. Please join us at the ASHP Midyear Clinical Meeting to discover new horizons in patient-controlled analgesia (PCA) and insulin therapy. On Monday, December 5, 2005, from 11:15 a.m. to 1:45 p.m., we will be presenting *Patient-Controlled Analgesia: Making It Safer for Patients*, sponsored by Hospira. On Tuesday, December 6, 2005, from 11:15 a.m. to 1:45 p.m., we will be presenting *Improving the Safety of Insulin Therapy*, sponsored by Novo Nordisk. Preregistration is not required for either exhibitor theater, but seating is limited. For details, visit www.ismp.org.

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Maalox brand name extension causes confusion

A new formulation of MAALOX (aluminum-magnesium hydroxide and simethicone) known as Maalox Total Stomach Relief has reached pharmacy shelves. The product's package looks similar to regular Maalox, but it only contains bismuth subsalicylate. A pharmacist reported that she told her grandfather who was recovering from orthopedic surgery to take Maalox for nausea and upset stomach. Two days later, her grandfather developed black stools, which concerned the pharmacist because her grandfather had been taking low molecular weight heparin and aspirin since his surgery. The pharmacist's mother had unknowingly bought the Total Stomach Relief formula with bismuth subsalicylate for her grandfather. Her mother saw the name Maalox and thought she had the right product. The cause of the black stools was now apparent; bismuth subsalicylate can cause black stools and tongue.

If you look at the product labels, it's easy to see the potential for mix-ups. As an extension of the well-known Maalox brand, all the products are packaged in white plastic containers that are the same size and shape, and "Maalox" is highlighted on the front label panel of each product (see photo). However, in the case of Maalox Total Stomach Relief, the bismuth subsal-

icylate content statement is less prominent. Although a banner in the upper corner proclaims, "Great new look. Same great Maalox" (see photo), this is very misleading because the product only contains bismuth subsalicylate without calling attention to this change. Consumers are likely to believe that the newer product, labeled *maximum strength*, just works faster and better than the regular



Banner says "...Same great Maalox," but the active ingredients are different.

product, labeled *regular strength*. Warnings are listed on the back label panel, but it's easy to overlook noteworthy side effects (e.g., black stools and tongue) and warnings related to use by children or teens with flu symptoms, patients receiving oral anti-coagulants, and patients allergic to aspirin. As an over-the-counter "mono-graph" drug, Maalox does not fall under FDA regulatory control. However, we have contacted Novartis Consumer Health and they have agreed to look into the matter.

Please alert practitioners about brand-name extensions with Maalox, especially since hospitals will need to purchase the products in look-alike bulk bottles because Novartis has discontinued unit-dose containers. Patients should also be warned about brand name extensions and to check the active ingredients in these products before purchase, or to ask their community pharmacist for help.

Propofol continued

Establish a continuous monitoring process and assessment criteria (e.g., vital signs, oxygen saturation, ideally capnography) for nonventilated patients who are receiving propofol. Ensure that equipment is readily accessible at the point of care to maintain a patent airway, provide oxygen, intubate, ventilate, and offer circulatory resuscitation.

Conclusion. The debate about who should be allowed to administer propofol may continue, but one thing is clear: whenever propofol is used for sedation/anesthesia, it should be administered only by persons who are: (1) trained in the administration of drugs that cause deep sedation and general anesthesia, (2) able to intubate the patient if necessary, and (3) not involved simultaneously in the procedure itself.

References: (1) Marshall S. Pleasant dreams: office surgeries fuel demand for anesthesiologists. *Crain's New York Business*. January 10, 2005. (2) Meltzer B. RNs pushing propofol. *Outpatient Surgery*. 2003;4(7). (3) WFTS ABC Action News. Doctor still on the hook for 'accidental' surgery death. *ABC Action News Tampa-St. Petersburg*. March 18, 2004.



8th Annual ISMP Cheers Awards

Tuesday Evening, December 6, 2005

Join us at Cili Restaurant & Bar at the Bali Hai Golf Club, Las Vegas, NV

(Awards dinner held during the 2005 ASHP Midyear Clinical Meeting)

The Institute for Safe Medication Practices (ISMP) is pleased to announce its **8th Annual Cheers Awards** winners and **Lifetime Achievement Award** recipient. The **Cheers Awards** honor individuals, organizations, and companies that have set a superlative standard of excellence for others to follow in the prevention of adverse drug events. Please join us on December 6, 2005, as we honor this year's award winners:

- Association of Perioperative Registered Nurses (AORN), Denver, CO
- CLARION: Students Building a Better Healthcare System Together, Minneapolis, MN
- Patient Safety Rounds Program at Dana-Farber Cancer Institute, Boston, MA
- Fostoria Community Hospital, Fostoria, OH
- John Gosbee, MD, MS, Director, Patient Safety Systems, National Center for Patient Safety, VHA, Ann Arbor, MI
- Johns Hopkins Community Physicians, Baltimore, MD
- Joanne Kowiatek, RPh, MPM, Manager, Medication Safety, University of Pittsburgh Medical Center, Pittsburgh, PA
- David Marx, JD, President, Outcome Engineering LLC, Plano, TX
- St. John's Mercy Medical Center, St. Louis, MO
- Target Corporation, Minneapolis, MN
- Lorri Zipperer, Cybrarian, Zipperer Project Management, Evanston, IL

Subscriber Award

The ISMP Medication Safety Alert! **Subscriber Award** is being presented to **The Cleveland Clinic Foundation**, in Cleveland, OH, in recognition of its successful large-scale implementation of selected recommendations from the *ISMP Medication Safety Alert!*[®] newsletter to prevent patient harm.

Lifetime Achievement Award

The ISMP **Lifetime Achievement Award** is being presented to **Herbert S. Carlin, DSc**, Vice President, Pharmaceutical Management Insight, Inc. The award honors individuals who, throughout their careers, have made ongoing contributions to patient safety. Dr. Carlin has a long history of providing outstanding leadership on medication use issues, including influencing the safe naming and labeling of drug products through service on the United States Pharmacopeia's (USP) Nomenclature Committee and the FDA-USP Product Labeling Committee.

Keynote Speaker

This year's keynote speaker is **Billy Tauzin**, President and CEO of the Pharmaceutical Research and Manufacturers Association (PhRMA) since January 2005. Having successfully battled cancer himself, he brings to the position unique insight into what patients face as they search for hope and treatment. Before joining PhRMA, Tauzin served 13 terms in Congress, where he helped win passage of a Medicare prescription drug bill.

Support Appreciated

The ISMP **Cheers Awards** would not be possible without the generous support of committed sponsors. Your assistance is crucial if ISMP is to continue to honor those who have set standards of excellence in the prevention of medication errors. Please consider helping to ensure the future of the awards and continuation of ISMP's lifesaving work by making a donation.

To attend the event, or to make a tax-deductible donation to support the **Cheers Awards**, please visit ISMP online at www.ismp.org or call ISMP at 215-947-7797.