



ISMP

Medication Safety Alert!®

Community/Ambulatory Care Edition

Educating the Healthcare Community
About Safe Medication Practices



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Volume 4, Issue 9 ■ September 2005

Little patches...Big problems. Protecting children from unintentional harm - Part 2

In the August issue, we urged practitioners to thoroughly review the recent FDA Public Health Advisory and an alert from Janssen about updated safety information that has been added to the fentanyl patch (both **DURAGESIC** and generic brands) product labeling (links can be found at <http://www.ismp.org/MSAarticles/fdasafetyalerts.htm>). As noted by FDA, some healthcare providers and patients may not be completely aware of the dangers of these products and the important recommendations to safeguard their use. ISMP considers fentanyl a high-alert medication, which means that it is not necessarily more prone to errors, but when used in error it carries a greater risk of patient harm or death. In part 1 of this article, we shared some of the safety issues related to using fentanyl patches contrary to the product labeling. In part 2, we will highlight safety issues that could lead to unintentional harm in children and offer recommendations to safeguard fentanyl patches and protect children.

A few days after the FDA and Janssen releases, we heard from a grieving mother whose child died from a fentanyl patch exposure. The woman, who suffers from chronic pain due to Crohn's disease, told us that her 4-year-old son either used a discarded patch retrieved from the trash, or opened a pouch containing a patch from a box of stored patches, and applied one to his leg. She found him dead on the floor of a bedroom near an overturned trashcan that held torn pouches and disposed patches. It is unknown how long the patch was in place.

Proper storage and disposal of fentanyl patches is of utmost importance to protect children, and even pets, from gaining access to this medication. Unfortunately, practitioners may not address these issues with patients or caregivers who are responsible for the patches. The FDA Advisory, as well as product labeling, specifically mentions that patches should be stored in a safe place and out of the reach of children. However, the lack of child-resistant packaging significantly contributes to the problem of safely storing patches. Five pouches are contained within a simple cardboard box and each patch is packaged in a pouch that is notched and easily
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In response to hurricane Katrina and the devastation it brought to Louisiana, Mississippi, and Alabama last week, we join hands with all Americans and our friends around the world to offer our deepest sympathies to families, friends, and colleagues who have lost loved ones, pets, homes, and jobs. We salute those who are helping with rescue and relief efforts, and the many others who will join the long journey of restoring health and repairing lives, homes, and cities.



Safety Briefs

■ **Up-to-date medication records necessary!** A hospital pharmacist received an order for fluoxetine 100 mg PO BID for a newly admitted patient. Upon verification, the pharmacist called the prescriber to discuss the high dose, but he had left for the day. The nurse told the pharmacist that the patient was on this dose at home and that an out-of-state psychiatrist had prescribed it. The drug and dose were also listed on the history and physical in the patient's chart. The pharmacist continued to express concern about the dose and asked the patient's wife to bring in the medication. The drug was identified as fluvoxamine 100 mg and the on-call physician was contacted to clarify the order.

Fortunately, due to the pharmacist's persistence, this error did not reach the patient. However, errors like this—mistakes when obtaining a history of the patient's home medications—are precisely the reason why we need to remind (and possibly assist) patients to keep an up-to-date record of all their medications (including any vitamins, nutritional products, and over-the-counter products) and encourage them to share this list with their healthcare providers. In an effort to reduce these types of errors, the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has initiated a National Patient Safety Goal that requires accredited organizations (both inpatient and outpatient) to accurately and completely reconcile medications across the continuum of care. Practitioners must obtain and document a complete list of the patient's
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Fentanyl patches (cont'd from previous page)

torn open by hand. Although healthcare practitioners realize the importance of keeping medication out of the reach of children, how often do we remind our patients of this? Likewise, knowing that children learn by example, practitioners should reiterate to patients the importance of not taking, or in this case applying, medication in front of children. As the mother who lost her 4-year-old son noted, children might equate applying a patch with putting on a sticker, Band-Aid, or temporary tattoo—a factor she believes played a role in her son's death. To prevent a similar tragedy, the risk management plan for fentanyl patches should be revised to require the use of child-resistant packaging by manufacturers and/or pharmacists. However, until changes occur, encourage patients (especially those who may have children or grandchildren in their homes) to store patches in a locked cabinet out of the reach of children.

According to the prescribing information, used patches or those that are no longer needed should be disposed of by folding the sticky sides together and then flushing them down the toilet. In this case, the mother was actually educated about proper disposal, but after her toilet clogged several times, she decided not to use this method. She was also concerned that the chemicals in the medication might have a negative effect upon the environment, as she had recently read. In addition to child-resistant packaging, the revised risk management plan should also require that a supply of biohazard containers that cannot be opened be provided to patients for patch disposal. We have been in contact with FDA about these recommendations and were told that changes to the Duragesic (and generic transdermal fentanyl) risk management plan are being considered. In the meantime, if there is a concern with using the toilet for disposal, pharmacists could consider periodically providing patients with a small oral liquid bottle with a child-resistant cap for disposal of used patches. Similarly, an empty soda can, a small sharps container, or some other container that is difficult to get into could be considered. Selecting or encouraging the use of a smaller container that is discarded frequently will minimize the number of patches that could be available to cause harm.

Safety packaging is already available with other products. For example, the US Consumer Product Safety Commission requires child-resistant packaging for **LIDODERM** (lidocaine patch 5%). Each patch is packaged in a pouch that must be opened using scissors. **NICODERM** (trans-*cont'd on page 3*

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current medications upon the patient's admission to the organization and *with the involvement of the patient*. This complete list is then communicated to the next provider of service when a patient is referred or transferred to another setting, service, practitioner, or level of care within or outside the organization. This new goal will make it absolutely necessary that acute care and ambulatory care practitioners establish an easy line of communication. Let's all do our part to ensure that patients are equipped with the right information!

■ **When is a “unit” really a “unit”?** A pediatric pharmacist alerted us to a pattern she noticed in which patients (or parents) have described growth hormone (somatropin) doses in units. When the pharmacist converted these “unit” doses to milligrams, she recognized that the stated doses were too high. Upon investigating this problem with one prescribing physician, she learned that these patients are actually using an insulin syringe to measure each dose, and the “units” they are reporting represents the volume of medication, not the dosage. For example, when questioning a patient who reported his dose as 14 “units,” the patient said that he drew back to “14” (0.14 mL) on an insulin syringe, as instructed by the physician who prescribed the drug. Thus, he believed his dose was 14 “units.” This problem is similar to potential confusion with **SYMLIN** (pramlintide acetate) doses as described in our June newsletter (“*Mg, mcg, units, mL: How will Symlin's safety measure up?*”). With Symlin, the manufacturer suggests using an insulin syringe to withdraw the proper volume to equal the prescribed microgram dose. But, despite education, it's predictable that a patient (or practitioner) will withdraw the Symlin dose in units (e.g., 30 units) instead of micrograms (e.g., 30 mcg). In the case of growth hormone, the drug may be prescribed in either milligrams or international units, causing further confusion.

Patients on growth hormone should be educated about the risk of confusion between international units and milligrams, especially if they're using an insulin syringe to measure the dose. They should be familiar with their prescribed dose and understand that an *cont'd on page 3*

Fentanyl patches (cont'd from previous page)

dermal nicotine) products contain a secure disposal unit for used patches. Also, Cephalon has a detailed risk management program for **ACTIQ** (oral transmucosal fentanyl citrate). The product is supplied in a child-protective blister pack, which can only be opened with scissors. A free welcome kit is provided to patients (call 800-505-4421), which includes a fanny pack with a lock to allow ready access to lozenges while securing them between usages. A child-protective storage container also provides a safe place to temporarily store partially used Actiq lozenges until they can be properly disposed; the lozenge can be inserted through a rubber stopper but cannot be retrieved. This type of comprehensive risk management program could help improve safety with transdermal fentanyl and should also reduce diversion and subsequent abuse of discarded patches, which is known to occur.

The recent Janssen alert mentioned that death and serious harm have occurred when people were accidentally exposed to fentanyl patches (i.e., transfer of a patch from an adult to a child while hugging, accidentally sitting or laying on a patch, caregiver exposure to medication in the patch during application or removal of the patch). In addition to the previous case, we have received other reports of pediatric accidental exposures. In one case, a child sat on a patch that had fallen off a family member and it adhered to her thigh. Another child removed a patch from his sleeping grandmother and applied it to himself. Fortunately, in these cases, the patches were noticed right away and the children were not injured. Numerous other reports involving cases of patches falling off or adhering poorly to patients have also been received, some from households with small children. Patients and their caregivers should be alerted to this possibility and reminded that the application site should be checked regularly to ensure that the patch is adhering properly. Product information recommends applying first aid tape along the edges of the patch if it does not stick well. Also, if a patch falls off, it should be discarded and replaced with a new one at a different site. We have been informed that one manufacturer provides **TEGADERM**-like dressings to patients who contact them about these issues.

In the October issue, we will conclude this series about fentanyl patches by addressing some of the many safety issues related to inadequate practitioner and patient education and offer additional recommendations to reduce patient harm.

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insulin syringe is only being used to measure the volume required for this dose. If the volumetric dose is large enough, patients should use a tuberculin syringe instead. (With minimal dead space in an insulin syringe, it may be preferable to a tuberculin syringe for low volume doses.) Some forms of growth hormone are also available in prefilled pen devices, which may help to reduce confusion.

■ **Salagen – Selegiline sound alike mix-up.** A home health nurse received a telephoned order from a dentist for an elderly patient experiencing problems related to dry mouth. The order was for **SALAGEN** (pilocarpine) 5 mg PO TID; however, when the nurse telephoned the pharmacist, the order was misheard and dispensed as selegiline 5 mg PO TID. Selegiline is a selective inhibitor of monoamine oxidase (MAO) type B used in the treatment of Parkinson's disease. About two weeks later, another pharmacist was processing a fentanyl patch prescription for this patient when the pharmacy computer system fired an alert about a drug interaction between fentanyl and selegiline. The error was recognized when the pharmacist contacted the prescriber about this interaction.

To avoid mix-ups related to sound-alike medications, all practitioners should be encouraged to use a process known as "read back" on every order that is communicated verbally or by telephone. With read back, an order is first transcribed as it was understood and then read back (or even spelled back for unfamiliar or sound-alike names such as these) to verify the correct interpretation. This is a requirement for those working in long-term care or home care operations accredited by JCAHO, but all practice sites should consider implementing this important safety step. The typical lack of access to clinical patient information by ambulatory care pharmacists also plays a role in these types of mix-ups, which is why it is so important for prescribers to indicate each medication's purpose when communicating orders to the pharmacy. If the purpose is not communicated, pharmacists should inquire about it when accepting the order. Additional recommendations can be found in our June 2003 article, *"Instilling a measure of safety into telephone and verbal orders."*

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Your Reports at Work!

In our January 2005 issue, we mentioned that several reporters had alerted us to the potentially confusing labeling of blister-packed **RISPERDAL M-TAB** (risperidone) Orally Disintegrating Tablets (see image on left). In their reports, they noted that the labels include instructions for opening the blister that are numbered 1 and 2 and that this has caused confusion due to the availability of 1 mg and 2 mg tablets. At these pharmacies where individual doses of medication were dispensed, mix-ups occurred when blister packs were removed from the original carton and placed in



Old Label

New Label

bins to allow easy access for dispensing and returning unused medication. At that time, we contacted Janssen to recommend a label change.

Since then, we received a similar report and again contacted Janssen. We are happy to inform you that they have agreed to make changes. As you can see, the product name and strength on the new label are much more prominent. Also, the administration directions are no longer numbered, reducing the risk of misreading the numbers as the dose. The new labeling will begin with the next batch of manufacturing, but it will probably take a few months to reach the marketplace.

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■ **Changed ophthalmic color-code.** For many years, **TIMOPTIC** (timolol) ophthalmic containers had different colored caps, depending upon the drug's concentration (light blue = 0.25%; yellow = 0.5%). However, some time ago, Merck started using yellow caps for both, based upon an update to a color-code system endorsed by the American Academy of Ophthalmology. The old system recommended either blue or yellow caps for beta-blockers. The new system recommends yellow caps for beta-blockers and dark blue caps for beta-blocker combinations. Products with the new color-coded caps are now beginning to reach pharmacy inventories. Concern has been expressed about the potential for using the wrong concentration if pharmacists, nurses, ophthalmologists, and optometrists are unaware of the change. ISMP has actively opposed color-coding of drug products for this reason, among others. Please alert other healthcare practitioners about this new potential for errors.

■ **Check it out!** To help increase dissemination of information and readership of FDA Safety Alerts, ISMP will post links to these alerts from our website home page. To review recent medication safety related communications from FDA such as recalls, public health advisories, and safety alerts, go to <http://www.ismp.org/MSAarticles/fdasafetyalerts.htm>.

Currently, the site contains information about iPLEDGE, the recently strengthened risk management program for **ACUTANE** (isotretinoin) and generic equivalent products. Other recent alerts include the FDA Advisory and an alert from Janssen about updated safety information that has been added to the product labeling of Duragesic and generic fentanyl patches. You will also find details about the recent recall by Perrigo Company that involves several different formulations of concentrated infants' oral drops packaged with a poorly designed oral syringe.

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