Institute for Safe Medication Practices

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ISMP Calls for More Action to Safeguard Pain Patches

Alerts, Labeling Changes Alone Not Enough to Protect Patients

HUNTINGDON VALLEY, Pa.— The FDA is investigating reported overdoses in patients using fentanyl transdermal patches for pain control. The Institute for Safe Medication Practices (ISMP) urges everyone who prescribes, dispenses, or administers fentanyl patches (both Duragesic and generic brands) to thoroughly review the July 15 FDA Public Health Advisory as well as last month's alert from Janssen. Without more education about the potential dangers of these products and important recommendations regarding their use, errors will continue to occur.

ISMP has repeatedly expressed concerns about using transdermal fentanyl without proper consideration of patient selection criteria, starting dose recommendations, contraindications, and administration procedures. The Institute's concerns were heightened recently as it received reports of several new incidents, two of which resulted in fatalities.

Recent Errors

A 77-year-old woman died in March due to misuse of a fentanyl patch. She was prescribed a fentanyl 50 mcg (per hour) patch to be applied every 48 to 72 hours. A friend picked up the prescription, but was not educated on how to use the medication. The woman applied the patch and placed a heating pad over the site of her pain, as was her usual practice. She was later found dead. In addition to applying heat to the patch, which is known to increase rate of absorption, it is suspected that she may have applied a second patch without removing the first.

A mother with chronic pain from Crohn's disease lost her 4-year-old son when he either used a discarded patch retrieved from the trash or opened a wrapper from a box of stored patches and applied one to his body. There have also been cases where children were accidentally exposed to patches that had fallen off or been taken off a sleeping relative.

ISMP also has received numerous reports of multiple patches being applied to hospitalized patients, which can happen if patches are overlooked (many are clear or translucent) or healthcare practitioners do not have a good system to remind them to remove patches before the next dose.

The attached newsletter article contains more details; please contact ISMP media relations at 704-321-3343 or rbrehio@ismp.org to arrange interviews with healthcare experts and/or individuals involved in fentanyl patch errors.

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Labeling changes
New product labeling addresses some of the issues involved in these errors. For instance, it notes that transdermal fentanyl should ONLY be used in patients who are already tolerant to opioid therapy of comparable strength. Labeling now also addresses the use of patches in patients with post-operative pain, dangers of using cut patches and applying heat source over area of patch, and safe disposal.

Additional Actions Needed
ISMP believes that the recent alerts could go a long way toward improving the safety of transdermal fentanyl, but only if healthcare practitioners become fully aware of the dangers, select patients appropriate for therapy, educate those patients on safe medication use, and ensure proper disposal of the product.

In addition to the alerts and current labeling changes, ISMP recommends creating:

- A risk management program that requires disposal of patches in biohazard containers that cannot be opened.
- Child-protected packaging for transdermal fentanyl (already available with other products such as lidocaine patches).
- Improved methods of documentation to help guard against applying multiple patches to patients in hospitals.
- A dosing calendar or wheel for patients to document the location and time of application and removal of patches at home.

For more information on ISMP's recommendations, contact Renee Brehio at 704-321-3343 or rbrehio@ismp.org. For the Janssen alert, go to www.fda.gov/medwatch/SAFETY/2005/duragesic_ddl.pdf For the July 15, 2005 FDA Public Health Advisory, go to www.fda.gov/cder/drug/advisory/fentanyl.htm.

About ISMP: The Institute for Safe Medication Practices (ISMP) is a 501c(3) nonprofit organization that works closely with healthcare practitioners and institutions, regulatory agencies, consumers, and professional organizations to provide education about medication errors and their prevention. ISMP represents more than 30 years of experience in helping healthcare practitioners keep patients safe, and continues to lead efforts to improve the medication use process. In 2004, the Institute celebrated the 10th anniversary of is official incorporation as a nonprofit organization. For more information on ISMP, or its medication safety alert newsletters for healthcare professionals and consumers, visit www.ismp.org

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