FDA issues updated safety warning regarding the inappropriate use of fentanyl transdermal (DURAGESIC) patches!

Fentanyl transdermal patches are in the news spotlight again, unfortunately it is for all of the wrong reasons. On December 21, 2007, the FDA issued an Update highlighting important information on the appropriate prescribing, dose selection, and safe use of the fentanyl transdermal system. This was a follow-up to a previous FDA Public Health Advisory and Information for Healthcare Professionals released in July 2005. Repeated warnings from professional and patient safety organizations, FDA alerts for similar fentanyl-based products, as well as the manufacturer’s Dear Health Professional letters and updated prescribing information has failed to slow the steady stream of reports of serious adverse events with fentanyl patches that included fatalities.

What’s causing these adverse events?
These adverse events are caused by inappropriate prescribing, dispensing and administration of the drug. Most alarming is the fact that this is not a new concern. As an example of the persistence of this important safety issue, the Institute for Safe Medication Practices (ISMP) reported that it has outlined the dangers of inappropriate use of fentanyl containing products in at least seven newsletter articles dating back to September 2001. In order to lessen the potential for further patient harm, it is imperative that all healthcare providers involved in prescribing and dispensing of these potent pain medications take time to review the latest FDA Update and incorporate all of the recommendations into their everyday practice.

Please take a minute to review important highlights from the FDA Update listed below regarding the safe use, storage and disposal of fentanyl transdermal patches.

Prescribers should:
• Be knowledgeable in the treatment of cancer and other chronic pain situations, as well as the appropriate use of fentanyl containing products.
• Utilize fentanyl transdermal patches for those patients who are OPIOID-TOLERANT ONLY! Patients are considered OPIOID-TOLERANT when they have a history of receiving opioid therapy for at least a week with a minimum total daily dosage equivalent to fentanyl 25mcg/hr patch (e.g. 60mg morphine, 30mg oxycodone, or hydromorphone 8mg daily).
• Utilize fentanyl transdermal patches for the management of persistent, moderate to severe chronic pain that requires continuous, around the clock opioid administration and which cannot be managed by other means (e.g. NSAIDs, opioid combination products or immediate release opioids).
• Be cautious of dosing patches every 48 hours since discarded patches pose a significant safety concern as well as a potential for abuse.

Fentanyl Transdermal patches are contraindicated in patients:
• Who are OPIOID-INTOLERANT.
• For the management of acute, post-operative, mild or intermittent pain.
• Who have acute or severe bronchial asthma or other instances of significant respiratory depression.
• With initial doses exceeding 25 mcg/h because of the need to individualize dosing.

Patients and their caregivers should be educated to:
• Store fentanyl patches in a safe place out of the reach of children to prevent both accidental exposure and possible diversion.
• Avoid applying a fentanyl patch in front of children as children learn by example and equate applying a patch with putting on a sticker, bandage or temporary tattoo.
• Avoid exposure to direct heat sources (e.g. heating pads, saunas, hot tubs, heated water beds, etc.) while wearing a fentanyl patch, as heat exposure may increase fentanyl absorption. Contact their physician should their body temperature exceeds 102F degrees
• Maintain a dosing calendar to keep tract of the location and time of patch application. Old patches should always be removed prior to the application of a new patch.
• Not cut or physically alter the patch in any way, as this will destroy the controlled release system
• Be aware of the signs of fentanyl overdose (e.g. respiratory distress, shallow breathing, tiredness, extreme sleepiness, sedation, inability to think, talk or walk normally).
• Properly handle and dispose of used patches by folding the patch upon itself and immediately flushing the patch down the toilet to prevent accidental exposure or diversion.

You can report any significant adverse events related to the inappropriate use of fentanyl to the FDA-MEDWATCH program at 1.800.FDA.1088 or on-line at http://www.fda.gov/medwatch/how/htm.

References:
• Tom, W. Safe use of fentanyl (Duragesic) Patches. PHARMACIST’S LETTER, Detail-Document #231010 October 2007.
• Anon. Ongoing, preventable fatal events with fentanyl transdermal patches are alarming! June 28, 2007. ISMP. Internet: www.ismp.org/newsletter/acutecare/articles/20070628.asp