FDA Alert for Healthcare Professionals

Fentanyl Transdermal Patch
(marketed as Duragesic)

FDA ALERT [07/2005]: Narcotic Overdose and Death

FDA is investigating reports of death and other serious adverse events related to narcotic overdose in patients using the fentanyl transdermal patch for pain control. In June 2005 the Duragesic product label was updated to add new safety information in several areas of labeling, and a "Dear Healthcare Professional" letter about these changes was issued by the manufacturer that is available at this link (http://www.fda.gov/medwatch/SAFETY/2005/duragesic_ddl.pdf). The directions for use of the fentanyl transdermal patch must be followed exactly to prevent death or other severe side effects from overdosing with fentanyl. These directions are provided in the product label and patient package insert at this link (http://www.fda.gov/cder/drug/infopage/fentanyl/DuragesicPPI.pdf).

This information reflects FDA's preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about this information. FDA intends to update this sheet when additional information or analyses become available.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program at 1-800-FDA-1088 or http://www.fda.gov/medwatch/report/hcp.htm

Recommendations

Health Care Professionals who prescribe the fentanyl transdermal patch should be fully aware of all the prescribing information in the product label. FDA is highlighting safety information from the product label here:

- **Fentanyl transdermal patches are potent opioid analgesics that may cause death from overdose. The fentanyl transdermal patch should always be prescribed at the lowest dose needed for pain relief.**

- **Fentanyl transdermal patches should not be used to treat short-term pain, pain that is not constant, or pain after an operation.** Fentanyl transdermal patches should only be used by opiod tolerant patients who are already taking other narcotic analgesics, and who have chronic pain that is not well controlled with shorter-acting analgesics.

- **Patients who are using the fentanyl transdermal patch and their caregivers must be fully informed about the directions for safe use of the patch.** These directions are provided in the product label and in the patient package insert, available at this link: http://www.fda.gov/cder/drug/infopage/fentanyl/DuragesicPPI.pdf.

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- **Patients who are using the fentanyl transdermal patch and their caregivers must be fully informed about safe methods for storage and disposal of used, unneeded or defective fentanyl transdermal patches.** Fentanyl transdermal patches should be stored in a safe place and kept out of the reach of children. Safely dispose of used, unneeded or defective fentanyl transdermal patches by folding the adhesive sides of the patch together (until it adheres to itself) and flushing it down the toilet.

- **Health care professionals who prescribe the fentanyl transdermal patch and patients who use the fentanyl transdermal patch and their caregivers should be aware of the signs of fentanyl overdose.** Signs of fentanyl overdose include trouble breathing or shallow breathing; tiredness, extreme sleepiness or sedation; inability to think, talk or walk normally; and feeling faint, dizzy or confused. If these signs occur, patients or their caregivers should get medical attention right away.

- **A patient using the fentanyl transdermal patch may have a sudden and possible dangerous rise in their body level of fentanyl or have a more potent fentanyl effect if they:** use other sedating medicines; drink alcohol (beer, wine or distilled spirits); have an increase in body temperature or are exposed to heat; or use other medicines that increase the elimination half-life of fentanyl (such as cytochrome P450 3A4 inhibitors).

Data Summary

FDA recently conducted a review of fatalities reported to the voluntary adverse event reporting system that were possibly due to unintentional overdose from the fentanyl transdermal patch. In many cases, establishing whether the overdose was unintentional was difficult, because the information provided in the report was incomplete and patients who were being treated with the fentanyl patch often had underlying diseases or conditions that could have contributed to their deaths (such as cancer). Factors identified as possibly related to unintentional overdose included: use of high doses of the fentanyl patch and/or multiple patches (sometimes in combination with other drugs), possible medication errors, accidental exposure (e.g., coming in contact with a discarded patch), application of a heat source to the patch possibly resulting in increased fentanyl absorption, injection or ingestion of the patch contents, and suspected transdermal patch malfunction (e.g., leaking patches). In addition, several patients reported poor adhesion of the patches to the skin.

The Duragesic product label addresses issues regarding proper use of the product (e.g., risk of abuse and diversion, avoidance of direct heat sources to the patch, proper disposal of a discarded patch). FDA continues to work with the manufacturers of these products to identify and manage factors that contribute to fentanyl overdose from use of the fentanyl transdermal patch.