

Recall of Painkiller Patch Widened

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04/08/04 - Janssen Pharmaceutica has announced what the company called an "urgent" expansion of its recall of its painkiller patch Duragesic because of a leak that could cause life-threatening complications.

Janssen originally announced the recall of one batch in February, but now the recall has widened to four more batches.

The transdermal patches contain the opioid fentanyl in gel form. **The company discovered that a seal along one edge allowed the drug to leak onto the skin. As a result, users could either be not getting enough, which can lead to withdrawal systems, or too much, which can lead to dangerous overdoses.**

The recall applies to Duragesic patches releasing 75 micrograms per hour. The control numbers listed on the package are: 0327192, 0327193, 0327294, 0327295, and 0330362. Patients and caregivers who are exposed to the gel are urged to wash their hands with water only; soap should not be used.

Pain Relief Patch Studied In 120 Deaths

Los Angeles Times - Ricardo Alonso-Zaldivar

07/16/05 - Federal regulators are investigating about **120 reported deaths** that may be linked to overdoses from a pain relief patch that administers a potent narcotic through the skin, the Food and Drug Administration said Friday.

Johnson & Johnson's Duragesic patch can provide up to three days' relief from severe chronic pain, such as that experienced by bone cancer patients. But fentanyl, its active ingredient, is highly dangerous. An overdose of the morphine-like drug can put a patient into a coma and shut down breathing.

Fentanyl gained international notoriety in 2002, when Russian authorities trying to end a hostage crisis at a Moscow theater pumped in a gas reportedly containing the drug, intending to put the hostages and their Chechen captors to sleep. Of the 750 hostages, about 120 died, nearly all from breathing the gas.

FDA officials said they are investigating whether the deaths among U.S. patients could be the result of unintentional fentanyl overdoses. Such overdoses could come

about if patients and doctors do not faithfully follow a series of precautions contained in the prescribing literature, or label, for the drug.

Other possible explanations include rare problems or defects with the patches themselves that would cause too much of the drug to be released into the body too quickly.

Doctors and patients should be aware of the signs of fentanyl overdose, which include trouble breathing or shallow breathing, tiredness, extreme sleepiness, inability to think, talk or walk normally and feeling faint, dizzy or confused, the FDA said. Patients experiencing these symptoms should get medical attention right away, the FDA said.

FDA officials said the agency announced the investigation in keeping with its new commitment to give the public warning of possible problems with prescription drugs. The FDA has been strongly criticized for taking too long to respond to evidence of heart attack risks with Vioxx and other arthritis drugs, and to evidence of suicide risks for teenagers taking anti-depressants.

The fentanyl investigation is in its early stages, FDA officials said, and the agency has reached no decision on whether the patches should be recalled, or their use limited. But the FDA did issue a new public health advisory Friday underscoring the need for patients to follow precautions for using the drug scrupulously.

Because of its risks, Duragesic and its generic equivalent already carry a so-called "black box" warning, the FDA's most emphatic.

On Friday, the agency underscored those warnings.

Doctors should prescribe the lowest effective dose of the medication, said the agency. And **fentanyl patches should not be used to treat short-term pain, or pain after an operation.** Patients should not attempt to use any patches that are damaged or broken. And they should not drink alcoholic beverages or bask in the sun while taking the drug because alcohol and a rise in body temperature can accentuate the effects.

Deaths Seen With Fentanyl Narcotic Pain Patch

WebMD - Michael Smith, MD

07/15/05 - The FDA today has issued a health advisory regarding the safe use of fentanyl skin patches (brand name Duragesic) in response to reports of deaths in patients using this potent narcotic medication for pain management.

The FDA is conducting an investigation into the deaths associated with these patches. It's unclear if the deaths are due to inappropriate use of the patch or factors related to the quality of the product, according to the advisory.

Deaths and overdoses have occurred in patients using both the brand name product Duragesic and the generic product fentanyl. The directions for using the fentanyl skin patch must be followed exactly to prevent death or other serious side effects from overdosing with fentanyl, according to the FDA.

Safety Information You Need to Know

Some patients and doctors may not be fully aware of the dangers of this very strong narcotic painkiller. Therefore, the FDA is highlighting the following important safety information:

* Fentanyl skin patches are very strong narcotic painkillers that may cause death from overdose. The fentanyl skin patch should always be prescribed at the lowest dose needed for pain relief.

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

* Patients who are using the fentanyl skin patch should follow their doctor's and pharmacist's directions exactly.

* Patients who are using the fentanyl skin patch should safely store and dispose of used, unneeded, or defective fentanyl skin patches. Fentanyl skin patches should be stored in a safe place and kept out of the reach of children. Safely dispose of used, unneeded, or defective fentanyl skin patches by folding the sticky side of the patch together (until it sticks to itself) and flushing it down the toilet.

Signs of Overdose

Patients who use the fentanyl skin patch should be aware of the signs of fentanyl overdose: 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 skin patch may have a sudden and possible dangerous rise in their body level of fentanyl or have a stronger effect from fentanyl if they:

- * Use other medicines that affect brain function
- * Drink alcohol (beer, wine, or distilled spirits)
- * Have an increase in body temperature or are exposed to heat
- * Use other medicines that affect how fentanyl is broken down in the body.

Patients should discuss all the above factors with their doctor or pharmacist.

Duragesic Patch Overview

www.injuryboard.com

The Duragesic patch is indicated for the management of severe, chronic pain (such as cancer pain) that cannot be managed with less powerful drugs such as acetaminophen-opioid combinations and nonsteroidal analgesics. Moreover, only patients who are already on and tolerant to opioid therapy, and who require continuous opioid administration should use the patch. Approved by the U.S. Food and Drug Administration (FDA) in 1990, Duragesic releases fentanyl, a strong opioid, through the skin at a fixed rate for 72 hours. The patch is made by Janssen Pharmaceutica and available by prescription only.

A boxed warning indicates that Duragesic is **NOT to be used in the following circumstances:**

- to manage acute or postoperative pain, including pain after outpatient surgery
- for mild or intermittent chronic pain that can be managed with less powerful drugs
- at a dose higher than 25 micrograms per hour
- by children under age 12
- by patients under age 18 who weigh less than 110 lbs.

Side effects include, but may not be limited to, nausea, vomiting, [constipation](#), drowsiness, weakness, dry mouth, [hypotension](#) and loss of appetite. Users are warned to avoid exposure to external heat sources such as heating pads and electric blankets, hot tubs, heated water beds, heat lamps, etc., because of a potential for temperature-dependent increases in fentanyl release that may lead to an overdose.

In February 2004, Janssen and the FDA notified healthcare professionals of a Class I recall of DURAGESIC 75 mcg/h. Only Control Number 0327192 (expiration October 2005) is subject to this recall. A potential seal breach on one edge may allow the drug to leak from the patch and could result in an increased absorption of the opioid component, fentanyl, leading to increased drug effect, including [nausea](#), sedation, drowsiness, or potentially life threatening complications. Conversely, if the hydrogel contents leak out of the patch, there may not be adequate medication to treat the patients' pain. In an opioid tolerant patient, this may lead to withdrawal symptoms, which include sweating, sleeplessness and abdominal discomfort. Over 400,000 patches are included in the recall.

In April 2004, Janssen expanded the Duragesic patch recall to include a total of 2.2 million patches. Health officials believe that over 20 percent of the recalled patches are still in use.

In July 2005, the FDA issued a Public Health Advisory regarding the safe use of transdermal fentanyl patches in response to reports of deaths in patients using this potent narcotic medication for pain management. In addition, a patient information sheet and an alert to healthcare professionals were issued identifying several important safety precautions for the use of fentanyl transdermal patches. These safety precautions include but are not limited to patient education regarding signs of overdose, proper patch application, use of other medications while using the patch, safeguards for children, and proper storage and disposal.

The FDA is conducting an investigation into the deaths associated with these patches. The Agency has been examining the circumstances of product use to determine if the reported adverse events may be related to inappropriate use of the patch or factors related to the quality of the product. It is possible that some patients and their health care providers may not be completely aware of the dangers of these potent narcotic drug products and the important recommendations regarding their safe use.

The Agency is working closely with the manufacturers of fentanyl patches to fully evaluate the risks associated with their use and to develop a plan to help patients avoid accidental fentanyl overdose.

This is the html version of the file

<http://www.psychiatry.ufl.edu/aec/courses/test/Fentanyl%20CPDD05.pdf>.

Fentanyl Use and Abuse: New Emerging

Trends in Drug Abuse

Recent trends in the use and abuse of prescription opioids, including fentanyl, have been linked to a rise in prescription drug-related deaths in the state of Florida. Fentanyl is a synthetic opioid analgesic that possesses approximately 100 times the potency of morphine. Fentanyl has been employed clinically during the surgical anesthesia process as an IV anesthetic agent for many years due to its high potency and short duration of action. Fentanyl is also available in the form of a transdermal patch (Fentanyl Transdermal System, **Duragesic**®, Janssen Pharmaceutica Products, L.P.) for the treatment of persistent, moderate-to-severe chronic pain. The patch is designed to provide continuous, systemic delivery of fentanyl for 72 hours at rates of 25, 75 or 100 g/hr. Due to fentanyl's high abuse potential, reports of **Duragesic** abuse have increased in the state of Florida. **During the first six months of 2004, fentanyl was reported as an agent responsible for the cause of death in 59 decedents.** In addition to the placement of multiple patches on the body, users have devised techniques for the removal of the contents of the drug reservoir for oral, IV or smoked administration. Not only has there been an increase in reports of purposeful abuse of the medication, but reports of accidental overdose are also on the rise. In conclusion, efforts to address this escalating trend of abuse should be undertaken through minimization of drug diversion, effective physician and patient education on the appropriate use of the **Duragesic** patch, and the development of a drug delivery system with a fail-safe mechanism to prevent removal of drug.

A rise in the abuse of opioids has been documented as reported in the 2004 Report of Drugs published by Florida Department of Law Enforcement. Furthermore, a trend is emerging in the use and abuse of **Duragesic** (fentanyl) patches. The various administration techniques devised by users include the removal of patch contents to administer drug orally, intravenously or via smoking.

Reports of accidental overdoses have been seen with the misuse of patches.

In conclusion, abuse of fentanyl patches is escalating, and thus, steps should be taken through minimization of drug diversion, effective physician and patient

education of the use and disposal of **Duragesic** patches, new or used, and the development of a drug delivery system with a fail-safe mechanism to prevent removal of drug.

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Fentanyl Use and Abuse:

New Emerging Trends in Drug Abuse. CPDD, Orlando, FL. June 21, 2005

J&J Adds Warnings to **Duragesic Pain Patch Label**

NEW YORK (Reuters) Jul 11 - Johnson & Johnson Inc. has added

warnings to its **Duragesic** (fentanyl) pain patch label to include information about possible misuse and abuse, U.S. health regulators said on Friday.

Duragesic's label includes new information on interactions with central nervous system depressants and alcohol, according to a letter from J&J's Janssen unit posted on the U.S. Food and Drug Administration Web site.

The new labeling will warn that **Duragesic** is only for use in patients who are already tolerant to opioid therapy of comparable strength and that use in non-tolerant patients may lead to death from respiratory depression.

The warning may be seen in its entirety at

http://www.fda.gov/medwatch/SAFETY/2005/duragesic_ddl.pdf