

## FDA Drug Safety Communication

**Duragesic (fentanyl) pain patches:** FDA requiring color changes to prevent accidental exposure that can cause death

### Safety Announcement

- Fentanyl and generic pain patches can cause serious harm and death in children, pets, and others that accidentally come into contact with them.
- FDA is requiring color changes to Duragesic (fentanyl) pain patches that will allow people to see these patches more easily and help prevent accidental contact with them. Similar changes will be made to the generic versions of these patches.
- Patients should dispose of pain patches properly after use to prevent potential harm.
  
- Fentanyl is a strong prescription pain medicine that contains a narcotic drug called an opioid.
  - Even after use these patches contain high amounts of the narcotic pain medicine and can be harmful.
  - Patches can accidentally fall off and stick to someone in close contact, such as a child, and cause harm.
    - Ensure patch is stuck to the skin tightly enough.
    - Check periodically (i.e., at least once an hour) by sight or touch to make sure the patch is still sticking to the skin properly.
    - Tape down the edges of a patch that becomes loose, or cover the patch with a sticky adhesive film such as Bioclusive or Tegaderm.
  - FDA continues to learn of deaths from accidental exposure to fentanyl patches. Two children have died (see separate Data Summary) since our last safety warning in [April 2012](#).
  - Dispose of patches properly by:
    - Folding the patch so the sticky sides are together
    - Flush the folded patch down the toilet right away
  
- Patients should read the [Medication Guide and instructions for use](#) that comes with their fentanyl patch prescriptions from the pharmacy.
  - Anyone accidentally exposed to a fentanyl patch should immediately seek emergency medical attention or call the toll-free Poison Help Line at 1-800-222-1222
  - FDA's [Safe Use Initiative](#) is working to create awareness and educational opportunities about the safe storage and proper disposal of fentanyl patches.
  
- Health care professionals should inform patients and caregivers about the correct use of fentanyl patches, and explain the appropriate storage and disposal with each prescription.
  
- To minimize the risk of accidental exposure to fentanyl patches (Duragesic and generic), FDA is requiring:

- The manufacturers must print the name and strength of the drug on the patch in long-lasting ink.
  - The ink color must be clearly visible to patients and caregivers.
  - This ink color change should help patients easily find patches on their bodies and see if the patches have fallen off.
    - Patches that fall off could accidentally be touched, worn, or eaten by children or pets, causing harm or possible death.
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- FDA includes pharmacists, physicians, nurses, researchers, and other health care professionals. We also work with external experts. We protect public health by assuring drugs are safe and effective. .

## **Additional Information for Patients and Caregivers**

- Fentanyl patches can cause harm and death, in babies, children, adults, and pets that are accidentally exposed to the medicine in the patch. They continue to contain high amounts of strong narcotic pain medicine **even after use and can be dangerous.**
- Partially stuck patches may accidentally move from the patient to someone who touches the patient, such as a child.
  - Check the patch periodically (i.e., once an hour) by sight or touch to make sure the patch is sticking properly.
  - Tape down patches that become loose or cover them with a sticky adhesive film such as Bioclusive or Tegaderm.
- **Immediately seek emergency medical attention** or call the toll-free Poison Help Line at 1-800-222-1222 if anyone is accidentally exposed to a fentanyl patch.
- Store fentanyl patches and all other medicines in a secure location out of the sight and reach of children and others.
- **Do not put patches in garbage cans.** They may be easily found there by children and pets.
- **To properly dispose of pain patches,** fold the patch in half with the sticky sides together. Flush the folded fentanyl patch down the toilet right away.
- To dispose of unused patches you no longer need, use the following steps:
  1. Remove each unused patch from its protective pouch
  2. Remove its protective liner
  3. Fold the patch in half with the sticky sides together
  4. Flush the patch down the toilet
- Unused patches can also be disposed of through a medicine take-back program. Contact your household trash and recycling service to see if there is a medicine take-back program in your community. You can also visit the U.S. Drug Enforcement Administration's Web site for information on National Prescription Drug Take-Back Events.
- You should receive a Medication Guide and instructions for use and disposal from the pharmacy with each fentanyl patch prescription.
- Talk to your health care professional if you have any questions or concerns about the fentanyl patch.
- Report medication errors or side effects from fentanyl patches to FDA's MedWatch program, using the information in the "Contact FDA" box on the last page.

### **Additional Information for Health Care Professionals**

- Counsel patients and their caregivers about the appropriate use, storage, and disposal of fentanyl patches.
- To avoid accidental transfer of a partially adhered patch, advise patients and caregivers to intermittently verify (every hour or so) by sight or touch that the patch is still adhered to the patient and to re-secure patches that have become loose by taping the edges or using an adhesive film such as Bioclusive or Tegaderm.
- Advise patients and caregivers to immediately seek emergency medical attention or call the toll-free Poison Help Line at 1-800-222-1222 if someone is accidentally exposed to a fentanyl patch.
- Encourage patients and their caregivers to read the Medication Guide and Instructions for Use that are provided with their filled fentanyl patch prescriptions.
- Report medication errors or adverse events involving fentanyl patches to FDA's MedWatch program, using the information in the "Contact FDA" box on the last page.

## Data Summary

- To identify reports of accidental pediatric exposures to fentanyl patches, we searched the FDA Adverse Event Reporting System (FAERS) database for reports submitted between August 7, 1990 (date of first fentanyl patch approval), and April 16, 2012.
- We also searched the Centers for Disease Control and Prevention's (CDC) National Electronic Injury Surveillance System-Cooperative Adverse Drug Event Surveillance (NEISS-CADES) database for reports submitted between 2004 and 2010.
- 30 cases of pediatric accidental exposure were identified.
- Children came into contact with patches that were:
  - Loosely attached to or had fallen off of the intended wearer
  - Stored or disposed of improperly.
- Most of the cases described serious harm that resulted in death (n=10), or required hospitalization and medical intervention (n=16)
- In 28 cases, the reported child's age was 10 years or younger; the majority (n=19) involved children 2 years or younger
- The accidental exposures occurred at patients' homes as well as in health care settings where children were visiting patients.
- Since we issued an [Alert](#) in April 2012 to warn about accidental exposure to fentanyl patches, FDA has learned of two additional cases of death in children.
  - One case was related to improper disposal of the fentanyl patch into the household trash.
  - The other case involved the transfer of a patch from a parent to a child in close proximity.

## Contact FDA

1-800-332-1088      1-800-332-1088 FREE

1-800-FDA-0178 Fax

Report a Serious Problem

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**Regular Mail:** Use postage-paid [FDA Form 3500](#)<sup>20</sup>

**Mail to:** MedWatch 5600 Fishers Lane

Rockville, MD 20857