



### **FDA requiring color changes to Duragesic (fentanyl) pain patches to aid safety—emphasizing that accidental exposure to used patches can cause death**

#### **Safety Announcement**

**[9-23-2013]** The U.S. Food and Drug Administration (FDA) is requiring color changes to the writing on Duragesic (fentanyl) pain patches so they can be seen more easily. This is part of an effort to prevent accidental exposure to the patches, which can cause serious harm and death in children, pets, and others. Similar changes are being requested for the generic fentanyl patches. We are also reminding patients and health care professionals that fentanyl patches are dangerous even after they've been used because they still contain high amounts of strong narcotic pain medicine. Used fentanyl patches require proper disposal after use—fold the patch, sticky sides together, and flush it down the toilet right away.

Patients should be aware that patches that are not stuck to the skin tightly enough may accidentally fall off a patient and stick to someone in close contact, such as a child. To prevent this, patients should check periodically, by sight or touch, to make sure the patch is still sticking to the skin properly. Patients should tape down the edges of a patch that become loose or cover the patch with a sticky adhesive film such as Bioclusive or Tegaderm.

We continue to learn of deaths from accidental exposure to fentanyl patches, including two additional deaths in children (see Data Summary) since our last warning to the public in [April 2012](#) about this safety concern.

As part of our ongoing effort to minimize the risk of accidental exposure to fentanyl patches, we are requiring the manufacturer of Duragesic to print the name and strength of the drug on the patch in long-lasting ink, in a color that is clearly visible to patients and caregivers. The current ink color varies by strength and is not always easy to see. This change is intended to enable patients and caregivers to more easily find patches on patients' bodies and see patches that have fallen off, which children or pets could accidentally touch or ingest. The manufacturers of generic fentanyl patches are being requested to make similar changes.

In addition, our [Safe Use Initiative](#) is working to create awareness and educational opportunities for health care professionals, patients, and caregivers about the safe storage and proper disposal of fentanyl patches.

We urge patients to read the [Medication Guide and Instructions for Use](#) that comes with their fentanyl patch prescriptions. In addition to informing patients about the correct use of fentanyl patches, health care professionals should also explain to patients and caregivers the appropriate storage and disposal each time they write a prescription for these patches. 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.

### **Facts about fentanyl patches**

- A strong prescription pain medicine that contains a narcotic opioid
- Marketed under the brand-name Duragesic and also as generic products

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

- Fentanyl patches and all other medicines should be stored in a secure location out of the sight and reach of children and others.
- A patch that is only partially stuck on the skin may accidentally move from a patient to someone in close contact, such as a child. To prevent this, patients should check periodically, by sight or touch, to make sure the patch is still sticking to the skin properly. Tape down patches that become loose or cover them with a sticky adhesive film such as Bioclusive or Tegaderm.
- A used fentanyl patch still contains high amounts of strong narcotic pain medicine and can be very dangerous and even cause death, in babies, children, adults, and pets who are accidentally exposed to the medicine in the patch.
- Immediately seek emergency medical attention or call the toll-free Poison Help Line at 1-800-222-1222 for anyone accidentally exposed to a fentanyl patch.
- To properly dispose of a used fentanyl patch, fold the patch in half with the sticky sides together. Flush the used fentanyl patch down the toilet right away. Do not put these patches in a garbage can where they can be easily found by children and pets.
- For unused, leftover patches from a prescription that you no longer need, you should dispose of them using 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; and (4) flush the patch down the toilet.
- Unused patches can also be disposed of through a medicine take-back program. Contact your city or county government's 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 website for information on [National Prescription Drug Take-Back Events](#).
- Additional information about proper use and disposal is included in the [Medication Guide and Instructions for Use](#) that you are supposed to get 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 at the bottom of this 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 from a patient to someone in close contact such as a child, advise patients and caregivers to intermittently verify, 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 them 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 is 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 at the bottom of this 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, and also 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. Thirty 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, or that were 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). Twenty-eight cases reported the age of the child as 10 years or younger, with the majority (n=19) involving children 2 years or younger. The accidental exposures occurred at patients' homes as well as in health care settings where children accompanied adults to visit 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.