

Analgesic Skin Patches

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SAFER
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Warning

The NSW TAG's Safer Medicines Group draws your attention to a number of safety warnings issued following reports of deaths and serious side effects in patients using fentanyl skin patches. One report involves a 77 year old woman who applied her fentanyl patch and then applied a heating pad over the patch, which was also the site of her pain. She was later found dead. Her death was attributed to increased fentanyl absorption as a result of the heat pad and the suspected application of a second patch without removing the first. There has also been a report of the death of a patient's child who applied one of his mother's patches to his body, as well as reports of children who escaped serious mishap following self-application of the patches.

Health care providers who prescribe, dispense and administer **fentanyl** patches (Durogesic[®] Transdermal System) and **buprenorphine** patches (Norspan[®] Transdermal Patch) are strongly advised to review the alerts cited below and to ensure that patients and caregivers are aware of the safe and effective use of these medicines. Although the published alerts specifically refer to fentanyl patches, safety concerns and principles for use also apply to buprenorphine patches.

FDA Advisory

The US Food and Drug Administration (FDA) has issued a Public Health Advisory titled 'Safety Warnings Regarding Use of Fentanyl[®] Transdermal (Skin) Patches'. The issues identified in the Advisory are highlighted here. Wording has been modified to align with recommendations in relevant Australian Consumer Medicines Information (CMI) leaflets.

- Fentanyl skin patches are very strong narcotic (opioid) painkillers that may cause death from overdose. **Fentanyl skin patches should always be prescribed in 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 another narcotic painkiller (ie patients who are opioid tolerant) and who have chronic pain that is not well controlled with shorter-acting painkillers.
- **Patients who are using fentanyl skin patches and their caregivers should be told about the directions for safe use of the patch and should follow directions exactly.** Directions are provided in the Consumer Medicine Information leaflet.
- **Patients who are using fentanyl skin patches and their caregivers should be told about safe methods of storage and disposal 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. The CMI recommends storage in a locked cupboard at least one-and-a half metres above the ground. Dispose of used, unneeded or defective fentanyl skin patches by folding the sticky side of the patch together until it sticks to itself. The CMI recommends wrapping the folded patch and disposing it carefully in the garbage. The designated garbage should be stored out of the reach of children.
- **Health care professionals who prescribe fentanyl skin patches and patients who use fentanyl skin patches 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 straight away.
- **Patients using fentanyl skin patches may have a sudden and possibly 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; have an increase in body temperature or are exposed to heat; or use other medicines that affect how fentanyl is broken down in the body. These factors are described further in the Product Information.

Alerts

- FDA Public Health Advisory "Safety Warnings Use of Fentanyl Transdermal (Skin) Patches" (www.fda.gov/cder/drug/advisory/fentanyl.htm)
- Institute for Safe Medication Practice (ISMP) Medication Safety Alert "New Fentanyl Warnings: More needed to protect patients" (www.ismp.org/Newsletters/acutecare/articles/20050811.asp)
- Janssen's "Dear Healthcare Professional" letter (www.fda.gov/medwatch/SAFETY/2005/durogesic_ddl.pdf)
- Medication Safety Alert published in the Journal of Pharmacy Practice and Research (www.shpa.org.au/pdf/journal//mss1205.pdf)