



August 11, 2009

Medication Safety Alert

MEDICATIONS: Fentanyl transdermal system 100 mcg/hr

DOSAGE FORMS: Patches

ISSUE: Watson Pharmaceuticals issued a retail-level recall on Fentanyl transdermal system 100 mcg/hr patches. This recall affects lot 145287A only.

This recall was issued because two patches from this product lot were found to be leaking. The result is a possible release of fentanyl gel from the gel reservoir into the pouch in which the patch is packaged, exposing patients or caregivers directly to fentanyl gel. Per the approved product labeling, fentanyl is a potent Schedule II opioid medication. Fentanyl patches that are cut or damaged in any way should not be used. Exposure to fentanyl gel may lead to serious adverse events, including respiratory depression and possible overdose, which may be fatal.

Anyone who comes in contact with fentanyl gel should thoroughly rinse exposed skin with large amounts of **water only; do not use soap**. The manufacturer recommends immediately disposing of patches with cut edges by flushing them down the toilet, using caution **not to handle them directly**. Patches with a cut edge that have leaked gel will not provide effective pain relief.

Anyone who has 100 mcg/hr Watson fentanyl patches should check the box or foil pouch for the lot number stated above to see if they have patches that are being recalled. The cut edge in affected patches can be seen upon opening the sealed foil pouch that holds the patch.

This recall affects lot 145287A of Watson fentanyl 100 mcg/hr patches, NDC No. 00591-3214-72, five-count, and NDC No. 00591-3214-54, single patch only.

More information about this recall may be viewed at www.watson.com.