

Duragesic (fentanyl) Patches: Drug Safety Communication - Packaging Changes to Minimize Risk of Accidental Exposure

[Posted 09/23/2013]


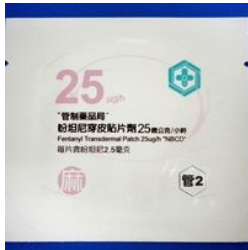

美國FDA要求改變Duragesic (fentanyl)貼片的字體顏色，使貼片能更容易地被看到。美國FDA持續獲知「接觸fentanyl貼片而意外死亡」的情形。

提醒病人及醫療人員，使用過的fentanyl貼片仍有危險性，因為貼片仍含有大量強效麻醉止痛藥。意外接觸到這些貼片，可能對兒童、寵物或其他人造成嚴重傷害或死亡。

為了減少意外接觸fentanyl貼片的風險，美國FDA要求製造商使用不易掉色且顏色清晰的墨水印製藥品名稱和劑量。此項變更，可使病人及醫療人員更容易看到病人身上的貼片、貼片脫落情形 (有可能造成兒童或寵物意外接觸或吞食)。

建議

病人應了解，貼片黏得不夠牢可能脫落，且黏到其他人。Fentanyl貼片使用後應妥善處置-將貼片的黏性面(含藥品成分)朝內對折。

狀態	目前停用	目前常備	目前常備
學名	Duragesic	吩坦尼	Duragesic
規格	50 mcg/h, 21 cm ²	25 mcg/hr, 15 cm ²	12 mcg/h, 5.25 cm ²
圖片			

[Posted 09/23/2013]

AUDIENCE: Pharmacy, Patient

ISSUE: FDA is requiring color changes to the writing on Duragesic (fentanyl) pain patches so they can be seen more easily. FDA continues to learn of deaths from accidental exposure to fentanyl patches.

Patients and health care professionals are reminded that fentanyl patches are dangerous even after they've been used because they still contain high amounts of strong narcotic pain medicine. Accidental exposure to these patches can cause serious harm and death in children, pets, and others.

In an effort to minimize the risk of accidental exposure to fentanyl patches, FDA is 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.

BACKGROUND: Duragesic (fentanyl) patch is a strong prescription pain medicine that contains a narcotic opioid. It is marketed under the brand-name Duragesic and also as generic products.

RECOMMENDATION: 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. Used fentanyl patches require proper disposal after use : fold the patch, sticky sides together, and flush it down the toilet right away.