



حيث أن الأطفال الصغار معرضون لخطر التعرض لهذه اللصقات الجلدية عن طريق الخطأ الغير مقصود بسبب الحركة الدائمة و شدة الفضول مما يزيد من فرصة حصولهم على هذه اللصقات و ابتلاعها أو لصقها على اجسادهم إذا لم يتم التخلص منها بطريقة صحيحة أو تخزينها بشكل سليم خصوصا أن هذه اللصقات لا تزال تحتوي على كمية كبيرة من مادة الفنتانيل .

وحرصا من الهيئة على سلامة المرضى فإنها توصي الممارسين الصحيين بضرورة تثقيف مرضاهم و مقدمي الرعاية الصحية حول الطرق المناسبة للتخلص من اللصقات الجلدية بعد استخدامها و تشجيع المرضى لمراجعة النشرة الداخلية للمستحضر و إتباع الإرشادات التالية في طريقة حفظ هذا المستحضر:

- يتم حفظ ملصق الفينتانييل في علبته الواقية عند درجة حرارة الغرفة ولا تُفتح العلبة إلا عند الاستخدام مباشرة.
- يتم حفظ ملصق الفينتانييل في مكان آمن بعيدا عن متناول الأطفال .
- يتم التخلص من ملصق الفينتانييل بعد استخدامه وذلك بطي الجانبين اللزجين من الملصق معا و رميه في المراض .

وتؤكد الهيئة العامة للغذاء و الدواء استمراريتها في متابعة ورصد كل ما يستجد من معلومات تخص سلامة و مأمونية المستحضرات الصيدلانية المستخدمة في المملكة. وللمزيد من المعلومات يمكن زيارة موقع الهيئة www.sfda.gov.sa كما تحث الهيئة العامة للغذاء والدواء ممارسي الرعاية الصحية على إبلاغ المركز الوطني للتيقظ والسلامة الدوائية عند حدوث أي أعراض جانبية أو أخطاء دوائية جراء استخدام الأدوية والمستحضرات ذات الإدعاءات الطبية، وذلك بإرسالها عن طريق البريد الإلكتروني أو عن طريق البريد المجاني على العنوان التالي:



المركز الوطني للتيقظ و السلامة الدوائية

الهيئة العامة للغذاء والدواء - قطاع الدواء

3292 الطريق الدائري الشمالي - حي النفل

الرياض 13312 - 6288

المملكة العربية السعودية

الرقم المجاني: 8002490000

هاتف: 012038222 تحويلة 2353. 2317. 2356,2340

فاكس: 012057662

بريد إلكتروني: npc.drug@sfda.gov.sa

وتقبلوا خالص التحية و التقدير ...

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نائب الرئيس التنفيذي لقطاع الدواء

٧١١٢

أ.د. صالح بن عبدالله باوزير
عنه د.هاجد بن محمد بن هاجد

Updates on Safety Information of Fentanyl patches - (Duragesic®)

As of the regulatory role of the Saudi Food and Drug Authority (SFDA) on drug post-marketing surveillance, the SFDA would like to share an important safety information with healthcare professionals (HCPs) and public about received an alerts of fatal cases resulting from accidental exposure of pediatrics to fentanyl patches.

Young children are at particular risk of accidental exposure to fentanyl patches. Their mobility and curiosity provide opportunities for them to find lost patches, take improperly discarded patches from the trash, or find improperly stored patches, all of which may result in patches being placed in their mouths or sticking to their skin. Exposure of young children to a fentanyl patch can lead to serious adverse events even death, due to the amount of fentanyl present in the patches. This can even occur with used patches which still contain a considerable amount of fentanyl.

SFDA Recommends Health care professionals to educate their patients and caregivers about the appropriate ways for disposal of Fentanyl patches after use and encouraging patients to follow the below instructions on the appropriate ways to keep this product:

- Store in original unopened pouch at room temperature.
- Keep a fentanyl transdermal system in its protective pouch until you are ready to use it.
- Keep fentanyl transdermal system in a safe place out of the reach of children.
- Dispose of fentanyl transdermal systems you no longer need. Open the unused packages, fold the sticky sides of the patches together, and flush them down the toilet.

Report Adverse Drug Events (ADEs) to SFDA:

The SFDA urges healthcare professionals and patients to report ADEs resulted from using such a medication and other medications either online, by regular mail or by fax, using the following contact information:

National Pharmacovigilance and Drug Safety Center (NPC)
Saudi Food and Drug Authority-Drug sector
3292 Northern Ring Road
Al Nafal District
Riyadh 13312 – 6288
Kingdom of Saudi Arabia
Toll free number: 8002490000
Tel: 012038222 ext. 2317, 2353, 2356, 2340, 5769
Fax: 012057662
Email: NPC.Drug@sfd.gov.sa

This is from dailymed

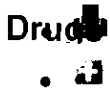
How should I store fentanyl transdermal system?

- Store in original unopened pouch at room temperature.
- Keep a fentanyl transdermal system in its protective pouch until you are ready to use it.
- **Keep fentanyl transdermal system in a safe place out of the reach of children and pets.**
- Dispose of fentanyl transdermal systems you no longer need. Open the unused packages, fold the sticky sides of the patches together, and flush them down the toilet





U.S. Food & Drug Administration



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FDA Reminds the Public about the Potential for Life-Threatening Harm from Accidental Exposure to Fentanyl Transdermal Systems ("Patches")

[4-18-2012] FDA reminds patients, caregivers, and healthcare professionals of the importance of appropriate storage, use, application, and disposal of fentanyl patches (including Duragesic and generic products) to prevent potential life-threatening harm from accidental exposure to the active ingredient, fentanyl.

Recently, FDA evaluated a series of 26 cases of pediatric accidental exposures to fentanyl patches reported over the past 15 years. Of these 26 cases, ten resulted in death and 12 in hospitalization. Sixteen of the 26 cases occurred in children two years old or younger.

Young children are at particular risk of accidental exposure to fentanyl patches. Their mobility and curiosity provide opportunities for them to find lost patches, take improperly discarded patches from the trash, or find improperly stored patches, all of which may result in patches being placed in their mouths or sticking to their skin.

Additionally, young children are at risk of exposure when being held by someone wearing a partially detached patch which can then transfer to the child. Exposure of young children to a fentanyl patch can lead to serious adverse events even death, due to the amount of fentanyl present in the patches. This can even occur with used patches which still contain a considerable amount of fentanyl.

The FDA previously alerted the public to the appropriate use and disposal of fentanyl patches in 2005 and 2006, following the receipt of reports of death and life-threatening adverse events related to fentanyl overdose. The adverse events occurred when the fentanyl patch was used to treat pain in patients who were not tolerant to opioids and when opioid-tolerant patients applied more patches than prescribed, changed the patch too frequently or exposed the patch to a heat source. In these advisories, FDA reminded patients, caregivers, and physicians about the appropriate use and disposal of patches.

Additionally, as part of a broader public awareness campaign about the proper disposal of medications in 2011, FDA advised consumers on the proper disposal of fentanyl patches when they are no longer needed. FDA recommends that the adhesive side of the patch should be folded together and then the patch should be flushed down the toilet.

Healthcare professionals are urged to educate their patients and caregivers about the appropriate use and disposal of fentanyl patches. Patients are encouraged to review the fentanyl patch product label for the instructions for use.

Healthcare professionals and patients should report any cases of accidental exposure to the FDA's MedWatch Safety Information and Adverse Event Reporting program.

- Complete and submit the report Online: www.fda.gov/MedWatch/report.htm
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

FDA continues to seek ways to minimize the risk of accidental exposure to fentanyl patches by working with our federal partners, manufacturers, and stakeholders to develop novel approaches to encourage appropriate use and disposal of fentanyl patches.