

Transdermal Fentanyl: Reminder about the Potential for Life-Threatening Harm from Accidental Exposure

The European Medicines Agency's Pharmacovigilance Risk Assessment Committee (PRAC) recently completed a review of global reports of accidental exposure to transdermal fentanyl patches. Accidental exposure to transdermal fentanyl can occur if a patch is swallowed or transferred to another individual. The recent review emphasised the need for safe handling of patches. Children are at risk as they may touch, suck, chew, or swallow a patch that has not been disposed of properly. In addition, children have a lower threshold for fentanyl overdose than adults.

Healthcare professionals are therefore reminded to provide clear information to patients and carers regarding the risk of accidental exposure by patch transfer, risk of accidental ingestion of patches and the need for appropriate disposal of patches. Patients and caregivers should be advised to follow the instructions on the patch carton and in the accompanying leaflet.

Advice to Healthcare Professionals

- Accidental exposure by patch transfer - Caution is needed to prevent accidental transfer of the fentanyl patch to a non-patch user, e.g., while being in close contact. Patients and carers should be advised that if a patch is accidentally transferred to another person, the transferred patch should be removed immediately and medical advice sought.
- Accidental ingestion - Patients and carers should be advised to choose the patch application site carefully and to monitor the adhesion of the patch closely, especially at the edges.
- Used patches - Used patches may still contain some active substance which could be potentially harmful to children and others. Patients and carers should be advised that used patches should be folded as soon as they are removed from the patient so that the adhesive side of the patch sticks firmly to itself before being disposed of safely.

- Please report any suspected cases of accidental exposure to fentanyl patches to the HPRAs via the on-line, downloadable or post-paid reporting options (www.hpra.ie).

Key message

Cases of accidental exposure to transdermal fentanyl in non-patch wearers, especially in children, continue to be reported. To prevent potential life threatening harm from accidental exposure to fentanyl, healthcare professionals are reminded of the importance of providing clear information to patients and carers regarding the risk of accidental exposure by patch transfer, risk of accidental ingestion and the need for appropriate disposal of patches.

Further details on transdermal fentanyl products are available at www.hpra.ie and www.ema.europa.eu/ema

HPRA Update

As highlighted in the 62nd edition of its Drug Safety Newsletter (DSN) published in June 2014, the Irish Medicines Board (IMB) changed its name to the Health Products Regulatory Authority (HPRA) at the beginning of July 2014, to more clearly reflect the wider scope of its work, functions and responsibilities across the health product sector.

The DSN will continue to be published by the HPRAs approximately 6 times per annum in electronic format, to highlight important regulatory updates to support the safe and appropriate use of medicines.

To continue to receive the DSN, please register on the HPRAs website (www.hpra.ie) to receive an alert when a new issue is published, or alternatively submit your email address to medsafety@hpra.ie to allow an electronic version to be emailed directly to you.