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16 June 2014

Direct Healthcare Professional Communication

TRANSDERMAL FENTANYL: Reminder about the potential for life-threatening harm from accidental exposure to transdermal fentanyl ("Patches")

Dear **Healthcare Professional**,

In agreement with the European Medicines Agency (EMA), the Malta Medicines Authority, Janssen-Cilag International NV would like to inform you of the following:

Summary

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

  <u>Accidental</u> exposure by patch transfer: Patients and caregivers should be advised that if a patch accidentally is transferred to another person, the transferred patch must be removed immediately.

  <u>Accidental ingestion</u>: Patients and caregivers should be advised to carefully choose the application site and check the adhesion of the patch.

  <u>Used patches</u>: Patients and caregivers should be advised that used patches should be folded so that the adhesive side of the patch adheres to itself and thereafter the patches should be safely discarded.

Further information on accidental exposure of transdermal fentanyl

The issue of accidental exposure is not a new safety issue. However, cases of accidental exposure do occur and in some instances have resulted in a fatal outcome (all concerned children). Recently the Pharmacovigilance Risk Assessment Committee (PRAC) performed an EU-wide review and observed that the lack of visibility of the patch may have contributed to these cases. Therefore, the PRAC has recommended that the visibility for fentanyl TTS (Transdermal Therapeutic Systems) be improved.

Caution is needed to prevent accidental transfer of the fentanyl patch to a non-patch user, e.g while sharing bed or being in close contact. To guard against accidental ingestion in children the application site should be carefully chosen and adhesion of the patch should be monitored closely.

In addition it is important that healthcare professionals provide clear information to patients on the safe handling of the patch. Patients should be informed on the importance to fold the patch so that the adhesive side of the patch adheres to itself, and thereafter the patch should be safely discarded.

Changes to the patch visibility are pending. In the meantime this communication is intended to remind you of the importance to share this information with colleagues, patients and caretakers.

Call for reporting

Any suspected adverse reactions and medication errors can be reported via the national Adverse Drug Reactions (ADRs) reporting system. Report forms can be downloaded from www.medicinesauthority.gov.mt/adrportal and posted to Medicines Authority Post-licensing Directorate, 203, Level 3, Rue D'Argens, Gżira GŻR 1368, MALTA, or sent by email to postlicensing.medicinesauthority@gov.mt

Company contact point

Contact point details for further information are given in the product information of the medicine (SmPC and Package Leaflet).

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