17th 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) and the Irish Medicines Board (IMB), the Marketing Authorisation Holders (MAH) listed below, 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 of providing clear information to patients and caregivers regarding the risk of accidental patch transfer and accidental ingestion of patches, and the need for appropriate disposal of patches:

- Accidental exposure by patch transfer: Caution is needed to prevent accidental transfer of the fentanyl patch to a non-patch user, e.g., while sharing a bed or being in close contact. Patients and caregivers should be advised that if a patch is accidentally transferred to another person, the transferred patch must be removed immediately and to seek medical advice.
- Accidental ingestion: Patients and caregivers 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: Even used patches contain some medicine which may harm children and others. Patients and caregivers should be advised that used patches should be folded as soon as they are removed so that the adhesive side of the patch sticks firmly to itself before being disposed of safely.

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 fatal cases concerned children). The Pharmacovigilance Risk Assessment Committee (PRAC) recently performed an EU-wide review and observed that the lack of visibility of the patch may have contributed to these cases. The PRAC has therefore recommended that the visibility of fentanyl TTS (Transdermal Therapeutic Systems) be improved.

As a result, changes to the patch visibility are pending. In the meantime this communication is intended to remind you of the importance of sharing this information with colleagues, patients and caregivers.

Call for reporting

Please report suspected adverse reactions to the IMB using the online system at www.imb.ie or alternatively using the freepost Yellow Card reporting system (FREEPOST, IMB Pharmacovigilance, Earlsfort Terrace, Dublin 2). Adverse reactions can also be reported to the IMB by calling (01) 6764971.

When reporting please provide as much information as possible, including information about medical history, any concomitant medication, onset and treatment dates.

Suspected adverse reactions may also be reported to the relevant Marketing Authorisation Holder (see contact details below).

Market Authorisation Holder	**Product Name**	**Email**	**Phone**	**Fax**
Janssen-Cilag Ltd	Durogesic DTrans	dsafety@its.jnj.com	+441494 567447	+44 1494 567799
Pfizer	Fentadur	eumedinfo@pfizer.com	180063363	
Rowex Ltd	Fental Matrix	pv@rowa-pharma.ie	027 50077	027 50417
Takeda	Matrifen Transdermal Patch	DSO-UK@takeda.com	1800 937970	+44 1628 526617

This information is being provided jointly by the above MAHs.

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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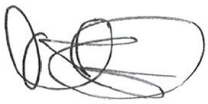

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