

18th June 2014

Transdermal fentanyl (“patches”): reminder of the potential risk of life-threatening harm from accidental exposure

Dear Healthcare Professional,

In agreement with the European Medicines Agency and the Medicines Healthcare product Regulatory Agency (MHRA), the Marketing Authorisation Holders listed below would like to inform you of the following:

Summary

- Accidental exposure to transdermal fentanyl can cause life-threatening harm.
- Accidental exposure can occur if a patch is swallowed or transferred to another individual.
- Cases of accidental exposure continue to be reported. Many cases involve children.
- To reduce this risk, it is important to advise patients and caregivers:
 - to choose the patch application site carefully (see instructions in the patient information leaflet)
 - to check the adhesion of the patch once applied, especially the edges
 - to fold the used patch as soon as it is removed so that the adhesive side of the patch sticks firmly to itself and dispose of the folded patch safely
 - if a patch is transferred to another person, remove it immediately and seek medical advice
 - if a patch is swallowed, seek medical help immediately

Further information

Accidental transdermal fentanyl exposure is not a new safety issue. However, cases of accidental exposure continue to be reported and in some instances have been fatal (all fatal cases concerned children).

In some cases, accidental exposure is thought to have occurred because the patches were not visible enough. Therefore the design of the patches will be changed to make them more visible. In the meantime, please advise patients and caregivers to take the actions listed above.

Call for reporting

Please continue to report any suspected adverse drug reactions to the MHRA through the Yellow Card Scheme: www.mhra.gov.uk/yellowcard

Alternatively, prepaid Yellow Cards for reporting are available:

- upon request by mail: FREEPOST YELLOW CARD
- at the back of the British National Formulary (BNF)
- by telephoning the Commission on Human Medicines (CHM) free phone line: 0800-731-6789
- or by electronic download through the Yellow Card section of the MHRA website

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

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

This information is being provided jointly by the following MAHs:

Marketing Authorisation Holder	Product Name	Email	Phone	Fax
Janssen-Cilag Ltd	Durogesic DTrans	dsafety@its.jnj.com	01494 567447	01494 567799
Actavis	Victanyl	medinfo@actavis.co.uk	01271 385257	
Dallas Burston Ashbourne Ltd	Fencino	enquiries@medinformation.co.uk	01858 525643/ 0870 192 3283	01858 525383
Mylan	Mylafent	info@mylan.co.uk	01707 853000	01707 664714
Pfizer	Opiodur	eumedinfo@pfizer.com	01304 616161	
Sandoz	Fentalis	uk.drugsafety@sandoz.com	01276 698020	
Takeda	Matrifen	DSO-UK@takeda.com	01628 537900	01628 526617
Tillomed	Tilofyl	info@tillomed.co.uk	01480 402400	0800 9706114
Zentiva	Osmanil	uk-drugsafety@sanofi.com	01483 554242	01483 554806

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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