Safeguarding public health

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DRUG ALERT

CLASS 1 MEDICINES RECALL

Action now – including out of hours

PATIENT LEVEL RECALL

Date: 29 September 2008 EL(08)A/13 Our Ref: MDR 49-09/08

Dear Healthcare Professional,

Janssen-Cilag Ltd

Ionsys Iontophoretic Transdermal System EU/1/05/326/001
Fentanyl 40 mcg per dose

Janssen-Cilag Ltd are recalling all Ionsys transdermal system stock, irrespective of batch number, to patient level. Some units of one batch of the transdermal system have been found to self-activate which has the potential to cause overdose.

Medical advice is that the device should be removed from patients immediately, alternative analgesia provided and patients monitored appropriately. Physicians and nursing staff in wards and ITUs should be informed so symptoms of toxicity may be promptly detected.

Medical information can be obtained from Janssen-Cilag Ltd, Medical Information Department on 0800 0323013.

All unused stock of Ionsys should be quarantined and returned for credit via the original supplier. For returns and credit enquiries, please contact Janssen-Cilag Ltd on 01494 567400.

No other Fentanyl products from Janssen-Cilag are affected and these may continue to be used.

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MHRA Distribution:
Regional Contacts for NHS Trusts and Provider Units
Chief Pharmacists: England, Scotland, Wales, Northern Ireland
Prison Health Policy Unit (DH)
Chief Pharmacists: Jersey, Guernsey, Alderney, Sark, Isle of Man, Gibraltar
Special Hospitals
Healthcare Commission for distribution to Independent Health Care Establishments
Primary Care Trusts (England)

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NHS hospital contacts were informed of this issue by the emergency telephone cascade on Sunday 28th September. Contacts were informed that further written details would be provided today.

All recipients are requested to cascade this information immediately even though the majority of this product is expected to be used post-operatively in hospitals.

Recipients of this Drug Alert should bring this to the attention of relevant contacts by copy of this letter. Primary Care Trusts are asked to bring this to the attention of relevant clinics, General Practitioners and Community Pharmacists by copy of this letter.

Yours faithfully

Ian Holloway

MHRA DMRC Manager