



FDA Adverse Event Reporting System (FAERS)

Case Details - Preferred Terms

Case Information:

Case #: 8360445 Version: 1 Case Type: DIRECT eSub: N HP: Country: USA Outcomes:
 FDA Rcvd Date: 24-Jan-2012 Init FDA Rcvd Date: 24-Jan-2012 Mfr Rcvd Date: MfrControl #: (A)NDA/BLA /

Patient Information:

Patient ID: Age (Yrs): Sex: Unknown Weight: DOB:

Suspect Products:

#	Product Name	Dose / Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event	ReC	DeC
1	FENTANYL	/		INJECTION					NA	NA
#	Product Name	Lot#	Exp Date	NDC#	Labeler					
1	FENTANYL				AMERIDOSE					

Event Information:

MedDRA® PreferredTerm	Start Date	End Date	Outcomes	Highlighted Terms
CIRCUMSTANCE OR INFORMATION CAPABLE OF LEADING TO MEDICATION ERROR DRUG LABEL CONFUSION MEDICATION ERROR				

Event / Problem Narrative :

Access Number: 63559

Description: Due to the drug shortage on Fentanyl. We ordered a different fentanyl syringe than we usually use (from Ameridose). Each syringe was labelled in large letters "50mcg/ml", then in smaller letters "2ml". Meaning the syringe contained 100mcg total per 2 ml. On the second day after we started using the new syringe (XX/XX/2011), there were 2 near misses reported to me (Medication Safety Officer). In both instances the nurses stated confusion over the new labels and that they almost gave their patient's 100mcg instead of 50mcg. We relabelled the syringes in the pharmacy as 100mcg/2ml to prevent any more confusion. Luckily no one received the wrong dose. The next shipment of fentanyl syringes we got from Ameridose already had the correct label on it (100mcg/2ml), so apparently they corrected the problem already. I think this another example of the problem with drug shortages and this error could potentially have been fatal had the nurses given the 2x overdose of fentanyl.

Medication Error



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Relevant Medical History:

Disease / Surgical Procedure	Start Date	End Date	Continuing?	Comment
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Medical History Products	Start Date	End Date	Indications	MedDRA® Preferred Term(s)
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Relevant Laboratory Data:

Test Date	Test Name	Result	Unit	Normal Low Range	Normal High Range	info Avail. Y/N
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Concomitant Products:

Product Name	Dose / Frequency	Route	Dosage text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
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Reporter Source:

Study Report	Study Name	Study Type	Sponsor Study	Protocol	IND #
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Literature Text:

Country of Event:

Sender MFR:

Reporter Name:

Reporter Type: Other

Reporter Org:

(b) (6)

Reporter Email: (b) (6)

Reporter Phone: (b) (6)

Reporter Street:

Reporter State: (b)

Reporter City:

Reporter Country: USA

Reporter Zip:

Sent To:

Health Prof.:

Identity Disclosed: Y

Occupation: