



FDA Adverse Event Reporting System (FAERS)

Case Details - Preferred Terms

Case Information:

Case #: 8480382 Version: 1 Case Type: DIRECT eSub: N HP: Country: USA Outcomes:
 FDA Rcvd Date: 23-Mar-2012 Init FDA Rcvd Date: 23-Mar-2012 Mfr Rcvd Date: MfrControl #: (A)NDA/BLA /

Patient Information:

Patient ID: (b) (6) 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	MORPHINE SULFATE	/	IV	INJECTABLE SYRINGE					NA	NA
2	HYDROMORPHONE HYDROCHLORIDE	/	IV	INJECTABLE SYRINGE					NA	NA
3	MIDAZOLAM	/	IV	INJECTABLE SYRINGE					NA	NA

#	Product Name	Lot#	Exp Date	NDC#	Labeler
1	MORPHINE SULFATE	01172012@242			AMERIDOSE
2	HYDROMORPHONE HYDROCHLORIDE	01062012@400			AMERIDOSE
3	MIDAZOLAM	12232011@337			AMERIDOSE

Event Information:

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

Event / Problem Narrative :

Access Number: 63770

Description: Location: Hospital Close-call: Look alike Sound alike medications Products involved: Morphine sulfate 2 mg/mL syringe (expiration date 4/16/2012 lot # 01172012@242) manufactured by Ameridose Westboro, MA Hydromorphone HCL 2 mg/mL syringe (expiration



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date 4/5/2012 lot # 01062012@400) manufactured by Ameridose Westboro, MA Midazolam HCL 2 mg/mL syring (expiration date 3/22/2012 lot # 12232011@337) manufactured by Ameridose Westboro, MA These medications look very similar. They are all 2 mg injectables. They all have black and white labels. They all have red caps. There has not been an incident in our facility regarding these medications but it is easy to see how these can be mistaken for one another. We recommend changing the colors of the labels and the caps to distinguish the different medications.

Medication Error

Relevant Medical History:

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

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)



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Case Details - Preferred Terms

Reporter Org:

(b) (6)

Reporter Email:

(b) (6)

Reporter Street:

Reporter City:

Reporter Zip:

Health Prof.:

Occupation:

Reporter State:

Reporter Country: USA

Sent To:

Identity Disclosed: Y

Reporter Phone:

(b) (6)