FDA Adverse Event Reporting System (FAERS)

Case Details - Preferred Terms

Case Information:

Case #: 8454452 **Version:** 1 **Case Type:** DIRECT **eSub:** Y **HP:** Y **Country:** USA **Outcomes:** OT

FDA Rcvd Date: 12-Mar-2012 **Init FDA Rcvd Date:** 12-Mar-2012 **Mfr Rcvd Date:** **MfrControl #:** **(A)NDA/BLA** /

Patient Information:

Patient ID: (b) (6) **Age (Yrs):** 65 **Sex:** Female **Weight:** 74.84 KG **DOB:** (b) (6)

Suspect Products:

#	Product Name	Dose / Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event	ReC	DeC
1	MIDAZOLAM	6 MG /	IV	6.0 Mg	PREOPERATIVE CARE	14-Feb-2012	14-Feb-2012	0	NA	NA
2	MIDAZOLAM	6 MG /	IV	6.0 Mg	SEDATION	14-Feb-2012	14-Feb-2012	0	NA	NA

#	Product Name	Lot#	Exp Date	NDC#	Labeler
1	MIDAZOLAM				
2	MIDAZOLAM				

Event Information:

MedDRA® PreferredTerm	Start Date	End Date	Outcomes	Highlighted Terms
DRUG EFFECT DECREASED				
PRODUCT QUALITY ISSUE				

Event / Problem Narrative :

midazolam 1mg/ml 2ml syringes x 3 patient presented for cardiac cath, midazolam 1mg/ml 2ml IV used for pre-procedure sedation. Patient was not sedated with this dose and required additionl 4mg to achieve adequate sedation. Patient also recieved 200mcg of fentanyl. Physician stated that he had noticed similar problems with other patients when using the midazolam 1mg/ml 2ml syringes prepared by ameridose ndc #24200-0562-44. Compounded medication used due to manufacturer backorder of Versed. One other physician also complained that his patients required more midazolam than usual. Ameridose was contacted about the potential problem and is conducting an investigation. WALKERC: |*********| 2012-03-12-07.48.17 |*********| USFDAMWVOLUNTARY_202814_15366_20120309.xml
Route To: AERS : Electronic Route To: DQRS : : Paper

Relevant Medical History:

Relevant Medical History:

None

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

Concomitant Products:

Product Name	Dose / Frequency	Route	Dosage text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
MIDAZOLAM	6 MG /	IV	6mg		2/14/12	2/14/12	0

Reporter Source:

Study Report	Study Name	Study Type	Sponsor Study	Protocol	IND #
S					

Literature Text:

Country of Event: USA

Sender MFR:

Reporter Name: (b) (6)

Reporter Type: Health Professional

Reporter Org:

Reporter Email:

Reporter Phone:

Reporter Street:

Reporter State: (b) (6)

Reporter City:

Reporter Country: USA

Reporter Zip:

Sent To:

Health Prof.: Y

Identity Disclosed:

Occupation: PHARM