



FDA Adverse Event Reporting System (FAERS)

Case Details - Preferred Terms

Case Information:

Case #: 8248349 Version: 1 Case Type: DIRECT eSub: Y HP: Y Country: USA Outcomes: OT
FDA Rcvd Date: 17-Nov-2011 Init FDA Rcvd Date: 17-Nov-2011 Mfr Rcvd Date: MfrControl #: (A)NDA/BLA /

Patient Information:

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

Suspect Products:

Table with 2 columns: Product Name, Dose / Frequency, Route, Dosage Text, Indication(s), Start Date, End Date, Interval 1st Dose to Event, ReC, DeC. Includes product ROPIVACAINE HYDROCHLORIDE.

Event Information:

MedDRA PreferredTerm Start Date End Date Outcomes Highlighted Terms
CAESAREAN SECTION
INADEQUATE ANALGESIA
MATERNAL EXPOSURE DURING PREGNANCY
MUSCULOSKELETAL PAIN
PRODUCT MEASURED POTENCY ISSUE

Event / Problem Narrative :

As reported to me by (b) (6) RN: Received complaint from provider (b) (6) regarding 2 of her patients + one other. Patients complained of shoulder pain from bolus dose and subsequent poor pain control from Ropiv 0.1% + fent 2 mcg/ml epidural. All 3 patients ended up having C-sections. They did not write down lot numbers. Current lot numbers of stock on hand in pharmacy include: 09162011@335, 09302011@407, 10182011@864. Notified manufacturer for investigation. Have attempted to contact Ameridose numerous times over the last several weeks to find the outcome of the investigation. I have still not received a response from them regarding the 3 lot numbers in question. Unable to determine if these are adverse events or a problem with the product -i.e. potency-. [REDACTED] ***** 2011-11-17-07.27.00 ***** USFDAMWVOLUNTARY_196290_9710_20111116.xml Route To: AERS : Electronic Route To: DQRS : Paper