

### FDA - Adverse Event Reporting System (FAERS)

#### **FOIA Case Report Information**

Case ID: 10213469

Case Information:

Case Type: EXPEDITED (15- eSub: Y HP: Country: USA Outcomes: OT, (A)NDA/BLA: 021977 /

DAY)

FDA Rcvd Date: 03-Jun-2014 Mfr Rcvd Date: 27-May-2014 Mfr Control #: US-SHIRE-US201402539

Patient Information:

Age: 10 YR Sex: Female Weight:

Suspect Products: Dose/

# Product Name Frequency Route Dosage Text Indications(s) Start Date End Date

1 Vyvanse Oral UNK, Unknown Attention

deficit/hyperactivity

disorder

Interval 1st

# Product Name Dose to Event DeC ReC Lot# Exp Date NDC # MFR/Labeler

1 Vyvanse U SHIRE

**Event Information:** 

Preferred Term ( MedDRA & Version: 17.0 ) ReC

Homicide

**Event/Problem Narrative:** 

(b) (6)

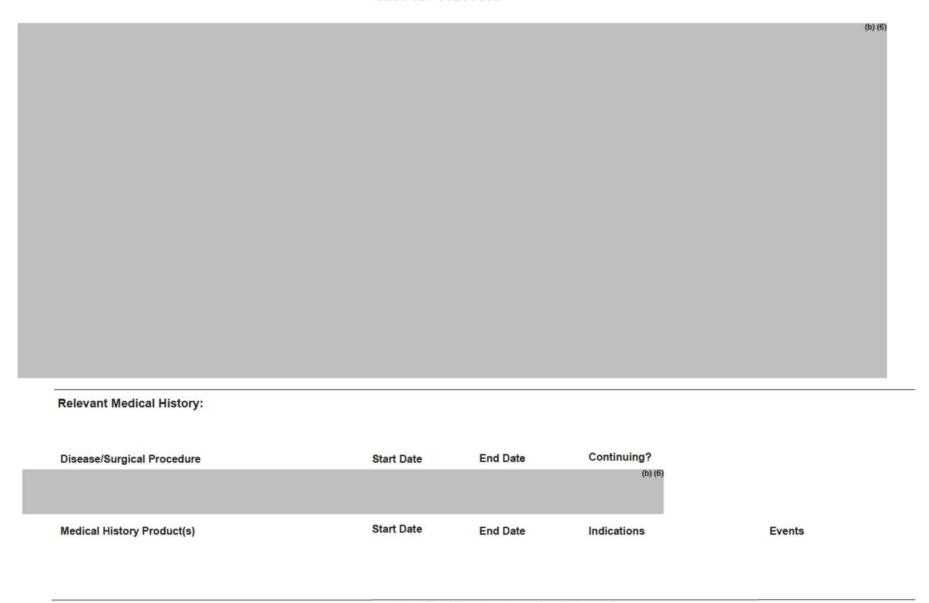


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Relevant Laboratory Data:

Test Name Result Unit Normal Low Range Normal High Range Info Avail

Concomitant Products:

# Product Name Dose/ Route Dosage Text Indications(s) Start Date End Date Interval 1st
Frequency Dose to Event

Reporter Source:

Study Report?: No Sender Organization: SHIRE

Literature Text:

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