

INDIVIDUAL SAFETY REPORT



3426984-6-00-01

OLUNTARY reporting CDER
with professionals of adverse
events and product problems

Form Approved: OMB No. 0910-0291 Expires: 11/30/99
See OMB statement on reverse

FDA Use Only

Triggers will
require #

114424

DEATH - FAX

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COER

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

A. Patient information

1. Patient identifier [redacted]	2. Age at time of event: 38 Years or Date of birth: _____	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or 85.3 kgs
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B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input checked="" type="checkbox"/> death 11/19/99 (mm/dd/yyyy)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event: 11/16/99 (mm/dd/yyyy)

4. Date of this report: 12/16/99 (mm/dd/yyyy)

5. Describe event or problem (up to a total of 6400 characters allowed)

38F with negative PMH admitted with fulminant hepatitis, likely secondary to excessive acetaminophen ingestion. Also acute renal failure, and DIC with GI bleed.

Foot surgery approx 5 D PTA. Patient's surgeon prescribed Vicodin 1-2 tabs q 4-6 h prn for post-op pain. Vicodin failed to relieve pain and a new Rx for Vicodin ES 1-2 tabs q 4-6 h prn pain issued. Later Darvocet N-100 was prescribed for pain unrelieved by Vicodin ES.

Acetaminophen ingestion was estimated by tablet count as follows:
 Vicodin ES #36 tabs = 27 G
 Vicodin #2 tabs = 1 G
 Darvocet N-100 #4 tabs = 2.6 G

6. Relevant tests/laboratory data, including dates (a total of 1000 characters allowed)

11/16/99 ED Admit Labs
 ALT 8579, AST 12,915
 T Bill 7.3
 Ca 6.1
 Acetaminophen 20.8, Salicylate 7.0
 INR 4.2
 Creatinine 4.1
 Bicarb 12

7. Other relevant history, including preexisting medical conditions (up to a total of 500 characters allowed)

Negative PMH

DSS

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C. Suspect medication(s)

1. Name (Product Name) (Labeled Strength) (Mfr/Labeler) #1 Vicodin / ES /	2. Dose/Frequency/Route used #1 2 tabs / q 2h / Oral	3. Therapy dates (if unknown, give duration) #1 From To (or best estimate) - 05/16/99
4. Diagnosis for use (separate indications with commas) #1 Post-op pain	5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	6. Lot # (if known) 7. Exp. date (if known) #1 #1
8. Event reappeared after reintroduction #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	9. NDC # (for product problems only) - -	10. Concomitant medical products and therapy dates (up to a total of 1000 characters)

D. Suspect medical device

1. Brand name	4. Operator of device <input type="checkbox"/> health professional <input type="checkbox"/> lay user/patient <input type="checkbox"/> other:
2. Type of device	5. Expiration date (mm/dd/yyyy) DEC 2 2 1999
3. Manufacturer name & address REC'D.	7. If implanted, give date (mm/dd/yyyy)
6. model # DEC 2 2 1999	8. If explanted, give date (mm/dd/yyyy)
catalog # MEDWATCH CTU	9. Device available for evaluation? (Do not send device to FDA) <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> returned to manufacturer on (mm/dd/yyyy)
serial #	10. Concomitant medical products and therapy dates (up to a total of 1000 characters)
lot #	
other #	

E. Reporter (see confidentiality section on back)

1. Name [redacted]	phone # [redacted]
Address [redacted]	E-mail (for electronic acknowledgment) [redacted]
2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no	3. Occupation Pharmacist
4. Also reported to <input type="checkbox"/> manufacturer <input type="checkbox"/> user facility <input type="checkbox"/> distributor	5. If you do not want your identity disclosed to the manufacturer, place an "X" in this box. <input checked="" type="checkbox"/>



Mail to: MEDWATCH ADVERSE EVENT REPORTING SYSTEM
 5600 Fishers Lane
 Rockville, MD 20852-9787

Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.

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MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Detail Reporter page - Page 2 63

E1. Reporter (detail information)

Last Name		First Name		Middle Initial
[REDACTED]		[REDACTED]		[REDACTED]
Title				
Pharmacist				
Organization		Department		
[REDACTED] Hospital		Drug Information Center		
Mailing Address - Street name, number, PO Box, rural route, mail route code designator, etc.				
[REDACTED]				
City		State	Zip Code	Country (if not USA)
[REDACTED]		[REDACTED]	[REDACTED]	United States
Telephone	Country Code	Area Code	Phone Number	Extension
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Fax	Country Code	Area Code	Phone Number	Extension
[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
E-mail Address				
[REDACTED]				

DSS
DEC 22 1999
ADVERSE EVENT REPORTING SYSTEM

Mail to: MEDWATCH or FAX to:
5600 Fishers Lane 1-800-FDA-0178
Rockville, MD 20852-0787

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THE FDA MEDICAL PRODUCTS REPORTING SYSTEM
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MEDWATCH

For VOLUNTARY reporting by health professionals of adverse events and product problems
Continuation page - Page 3 of 3

B5. Describe event or problem continued (up to a total of 6400 characters allowed)

The patient also took 20 tablets (by count of remaining tablets) of 12.5mg Phenergan, and 6 tablets of Ambien 10mg.

Alcohol ingestion as stated by family limited to an occasional cocktail at dinner. The patient was nauseated and constipated (likely due to quantity of hydrocodone) for 2-3 D PTA.

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ADVERSE EVENT REPORTING SYSTEM

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Rockville, MD 20852-9787

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