MEDWATCH

Individual Safety Report

3334005-9-00-01

LUNTARY reporting
professionals of adverse
and product problems

CDER

Form Approved: OMB No. 0910-0291, Expires 12/31/99
See OMB Statement on reverse

FDA use only
Triage unit
Assignment #
075577
108332

A. Patient information

1. Patient Identifier: [redacted] In confidence
2. Age at time of event: 46
Date of birth: [redacted]
3. Sex: ☐ female ☒ male
4. Weight: 150 lbs

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)
☐ death
☒ life-threatening
☒ hospitalization (initial)
☐ disability
☐ congenital anomaly
☒ required intervention to prevent permanent impairment/damage
☐ other:
3. Date of event: 04/09/97
4. Date of this report: 07/24/97
5. Describe event or problem

THE REPORTER STATED THAT THE PATIENT WAS TAKING FIORICET (SOCET) DILANTIN FOR APPROXIMATELY 2 MONTHS AND TOOK FIORICET (2 TABS) FOR A HEADACHE ON 4/8/97. HE BECAME VERY ILL, EXPERIENCED NAUSEA AND VOMITING WHICH WAS UNCONTROLLED. HE WAS ADMITTED TO THE HOSPITAL AND DIAGNOSED AS HAVING LIVER FAILURE. FIVE DAYS LATER, HE HAD KIDNEY FAILURE SECONDARY TO THE LIVER FAILURE. THE REPORTER FELT THAT THE COMBINATION OF DILANTIN AND ACETOMINOPHEN IN FIORICET WAS THE DIRECT CAUSE FOR THE LIVER FAILURE. THE PATIENT HAS BEEN HOSPITALIZED FOR OVER 100 DAYS AND IS DOING BETTER AT A REHAB CENTER.

AT [redacted]

THE BIOPSY OF THE LIVER SHOWED "TOXIC DAMAGE CONSISTENT WITH TYLENOL OVERDOSE". THE DAMAGE WAS NEW DAMAGE, NOT A ~~[illegible]~~ CHRONIC TYPE.

As of 8/6/97 he is still in rehab trying to regain the use of his right hand + to be able to walk again. He may have to have Achilles tendon release surgery to be able to walk.

6. Relevant laboratory data, including dates

	Result	Range
NONE 4/9/97 Acetaminophen	4	0-30 toxic > 12 24 hours after dose
4/9/97 Dilantin	16	10-20
4/9/97 15:45 Potassium	7.0	3.5-5.0
4/9/97 18:16 pH	~~5.6~~ 6.86	7.4

See attached reports

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

THE PATIENT HAS A HISTORY OF SEIZURE (UNKNOWN ORIGIN). DRUG ALLERGY TO CARAFATE, TEGRETOL, DEPAKOTE

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C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)
#1 DILANTIN (PARKE-DAVIS) PARKE-DAVIS
#2 FIORICET (GEN ISOCET-RUGBY)
2. Dose, frequency & route used
#1 400 MG QD
#2 2 TABS PO
3. Therapy dates (if unknown, give duration)
#1 02/12/97 - 04/09/97
#2 04/08/97
4. Diagnosis for use (indication)
#1 COMPLEX PARTIAL SEIZURE
#2 HEADACHE
5. Event abated after use stopped or dose reduced
#1 ☐ yes ☒ no ☐ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply
6. Lot # (if known)
#1 UKN
#2
7. Exp. date (if known)
#1 UKN
#2
8. Event reappeared after reintroduction
#1 ☐ yes ☐ no ☒ doesn't apply
#2 ☐ yes ☐ no ☐ doesn't apply
9. NDC # (for product problems only)
10. Concomitant medical products and therapy dates (exclude treatment of event)

NEURONTIN 300 MG 5 TIMES A DAY, AMBIEN 10 mg ÷ HS

D. Suspect medical device

1. Brand name
2. Type of Device
3. Manufacturer name & address

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4. Operator of device
☐ health professional
☐ lay user/patient
☐ other:
5. Expiration Date
6. model #
catalog #
serial #
lot #
other #
7. If implanted, give date
8. If explanted, give date
9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on
10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name & Address
[redacted]
[redacted] ST
Phone [redacted]

DSS
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2. Health professional? ☒ yes ☐ no
3. Occupation: RPH
4. Also reported to
☒ manufacturer
☐ user facility
☐ distributor
5. If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box. ☒

FDA

Mail to: MEDWATCH
5600 Fishers Lane
Rockville, MD 20852-9787

1-800-FDA-0178

FDA Form 3500 (1/00)

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

TAKEN BY TELEPHONE

CTU 108332

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CO.

Individual Safety Report

3334005-9-00-02

[redacted]

[redacted]

FAX [redacted]

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