Individual Safety Report

*3495238-4-00-01*

VOLUNTARY reporting
alth professionals of adverse
nts and product problems

Form Approved: OMB No. 0910-0291 Expires: 12/31/94
See OMB statement on reverse

FDA Use Only (MB)

Triage unit sequence # 121596

CDER

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E FDA MEDICAL PRODUCTS REPORTING PROGRAM OP

Page ___ of ___

## A. Patient information

1. Patient identifier: 192 in confidence
2. Age at time of event: 62 or Date of birth:
3. Sex: ☐ female ☒ male
4. Weight: ___ lbs or ___ kgs

## 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 ___ (mo/day/yr)
   - ☐ life-threatening
   - ☒ hospitalization – initial or prolonged
   - ☐ disability
   - ☐ congenital anomaly
   - ☐ required intervention to prevent permanent impairment/damage
   - ☐ other:
3. Date of event (mo/day/yr): 1/4/00
4. Date of this report (mo/day/yr): 3/6/00
5. Describe event or problem

Weakness, ↓ responsiveness. BP 65/50, ↑ LFTs, hypoxia Naloxone given. Toxic ingestion of Lortab elixir, prob. accidental. Given Mucomyst X ~ 16 doses Jan 4-7

## C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   #1 Lortab elixir
   #2
2. Dose, frequency & route used
   #1
   #2
3. Therapy dates (if unknown, give duration) from/to (or best estimate)
   #1 12/28 → 1/4/00
   #2
4. Diagnosis for use (indication)
   #1 Ca pain
   #2
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
   #2
7. Exp. date (if known)
   #1
   #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)

## D. Suspect medical device

1. Brand name
2. Type of device
3. Manufacturer name & address
4. Operator of device
   - ☐ health professional
   - ☐ lay user/patient
   - ☐ other:
5. Expiration date (mo/day/yr)
6. If implanted, give date (mo/day/yr)
7. If explanted, give date (mo/day/yr)

(...t send to FDA)

...nufacturer on ___ (mo/day/yr)

...tes (exclude treatment of event)

| | SPEC | ALKP | LDH | GOT | GPT | G-GTP |
|---|---|---|---|---|---|---|
| | 01/08/2000@20:05 PLA | 143 H | 260 H | 135 H | 391 H | |
| | 01/07/2000@11:39 PLA | 188 H | 230 H | 304 H | 580 H | |
| 6. | 01/07/2000@05:00 PLA | 183 H | 251 H | 355 H | 628 H | |
| | 01/06/2000@05:00 PLA | 216 H | 284 H | 792 H | 896 H | |
| | 01/05/2000@05:00 PLA | 347 H | 1157 H | 3687 H | 1776 H | |
| | 01/04/2000@13:20 PLA | 355 H | 5600 H | 7270 H | 2469 H | |
| | 01/04/2000@05:00 PLA | 350 H | 7810 H | 8230 H | 2810 H | |
| 7 | 01/03/2000@22:07 PLA | 308 H | 7540 H | 5350 H | 2153 H | |
| | 11/29/99 | 20 | — | 19 | 8 | 29 |

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MEDWATCH CTU

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...ction on back)

1. Name, address & phone # [redacted]

VA HOSPITAL (119)
7400 MERTON MINTER BLVD.
SAN ANTONIO, TX 78284

2. Health professional? ☒ yes ☐ no
3. Occupation: Pharm D
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

or FAX to: 1-800-FDA-0178

FDA Form 3500 (6/96) CTU 121596

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