RECEIVED AT DRUG SAFETY SURVEILLANCE

24-APR-1998-0923

For VOLUNTARY ... ofessionals of ac... d product probl...

1 of 1

Individual Safety Report

3072314-1-00

A. Patient information

1. Patient identifier	2. Age at time of event:	3. Sex	4. Weight
[redacted]9234 In confidence	or 69 Date of birth:	☐ female ☒ male	___ lbs or 89 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)

4. Date of this report (mo/day/yr)

5. Describe event or problem

Liver failure 2° APAP and/or metformin use

Pt transferred from Lake City VAMC 2° hepatic and renal failure. Admitted to LCVAMC 2/26 c̄ c/o 4 mth h/o exertional shoulder pain (pt's angina equivalent); intermittent PND, diaphoresis, tingling in (B) arms. Pt also c/o 2 mth h/o nausea/vomiting. UGI 2/17 revealed 4x5 mm antral ulcer. Pt noted to be in ARF and treated as CHF exacerbation. On 2/28 AST ↑ ↓ other evidence of hepatocellular damage. Pt * transferred to ~~GVAMC~~ unit ~~MCU. On arrival~~, pt unit where he became more confused. Transferred to GVAMC via EMS on lactulose.
Prob not 2° APAP as on chronic low dose ∴ presentation too late. ∅ APAP levels drawn

6. Relevant tests/laboratory data, including dates

AST (3/1) = 11984
(3/2) = 3485
ALT (3/1) =
(3/2) = 4860
alk Phos (3/2) = 231
LDH (3/2) = 2673
T. Bili (3/2) = 0.8
D. Bili (3/2) = 0.4
CK/MB (3/2) = 251/7.8
BUN/Cr (3/2) = 95/4
Abd U/S ⓟ

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

69 y/o WM c̄ PMH of CAD [S/P CABG (1986)]; DJD / fibromyalgia; NIDDM [on oral meds]; HTN; chronic sinusitis.
Allergy: tetracycline
2 PPD h/o tobacco

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
- #1 Metformin
- #2 Darvocet

2. Dose, frequency & route used
- #1
- #2

3. Therapy dates (if unknown, give duration) (from/to (or best estimate))
- #1
- #2

4. Diagnosis for use (indication)
- #1 NIDDM
- #2 DJD

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)

Persantine
Dectizine
NTG
Verapamil
Fosinopril
glyburide

D. Suspect medical device

1. Brand name 81679

2. Type of device

3. Manufacturer name & address

REC'D.
APR 24 1998
MEDWATCH CTU

4. Operator of device
- ☐ health professional
- ☐ lay user/patient
- ☐ other:

5. Expiration date (mo/day/yr)

6.
- model #
- catalog #
- serial #
- lot #
- other #

7. If implanted, give date (mo/day/yr)

8. If explanted, give date (mo/day/yr)

9. Device available for evaluation? (Do not send to FDA)
☐ yes ☐ no ☐ returned to manufacturer on ___ (mo/day/yr)

10. Concomitant medical products and therapy dates (exclude treatment of event)

E. Reporter (see confidentiality section on back)

1. Name, address & phone #

[redacted] VA MEDICAL CENTER
PHARMACY SERVICE (119)
1601 SW ARCHER ...
GAINESVILLE, FL 32608-1197

2. Health professional? ☒ yes ☐ no

3. Occupation: Pharmacy Resident

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 (6/93)

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