Individual Safety Report

3260240-4-00-01

VOLUNTARY reporting
ealth professionals of adverse
ents and product problems

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

FDA Use Only
Triage unit sequence # 102641

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A. Patient information

Patient identifier	Age at time of event:	Sex	Weight
[redacted] In confidence	69 years or Date of birth:	[X] female [ ] male	was lbs or does kgs

B. Adverse event or product problem

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

2. Outcomes attributed to adverse event (check all that apply)
   - [X] death 03/16/1999 (mo-day-yr)
   - [ ] life-threatening
   - [X] hospitalization - initial or prolonged 3/1/1999
   - [ ] disability
   - [ ] congenital anomaly
   - [ ] required intervention to prevent permanent impairment/damage
   - [ ] other:

3. Date of event (mo-day-yr): 03/16/1999

4. Date of this report (mo-day-yr): 5/4/1999

5. Describe event or problem

69 y/o female with chronic psoriasis, complicated by episodes of pustular psoriasis which required short course of oral prednisone and tegison (etretinate) at dose of 75 mg/day 12/1/1998. Prednisone stopped and tegison decreased to 10 mg/day - tolerated well. When latter removed from the market, patient changed to soriatane (acitretin) at low dose, usually 10 mg/day with good control of her psoriasis. In past she had ever elevation LFTs (only new Rx - Tylenol for arthritis). Then in February 99, marked elevation LFTs, soriatane stopped 2/5/99. Liver damage progressed, the Hepatorenal Syndrome developed and she underwent liver transplant.

6. Relevant tests/laboratory data, including dates

Elevation of liver function	ALT	AST	B.1
12/1/98	135	146	
5/1/98	88	90	
11/25/97	66	63	
2/5/99	322	1144	5.9
2/16/99	314	1226	10.5

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

1) obesity
2) Hypertension
3) psoriatic arthritis - on Motrin, but in Fall 98, started on high dose Tylenol (only new added medication)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
   - #1 SORIATANE 10 mg
   - #2 High dose Tylenol for arthritis TYLENOL

2. Dose, frequency & route used
   - #1 10 mg daily
   - #2 oral

3. Therapy dates (if unknown, give duration) (from/to or Last est. date)
   - #1 on Tegison/Soriatane x years
   - #2 recently added - Fall 98

4. Diagnosis for use (indication)
   - #1 pustular psoriasis
   - #2 psoriatic arthritis

5. Event abated after use stopped or dose reduced
   - #1 [ ] yes [X] no [ ] doesn't apply
   - #2 [ ] yes [X] 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 [X] doesn't apply
   - #2 [ ] yes [ ] no [X] doesn't apply

9. NDC # (for product problems only) - -

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

1) Cogard for hypertension.
2) Motrin for arthritis + Tylenol added

D. Suspect medical device

1. Brand name

2. Type of device DSS

3. Manufacturer name & address
   MAY 12 1999
   ADVERSE EVENT REPORTING SYSTEM

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

5. Expiration date (mo-day-yr)

6. RECD.
   model #
   catalog #
   serial #
   lot # MEDWATCH CTU
   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] MD
   [redacted] Ave
   [redacted]

2. Health professional? [X] yes [ ] no

3. Occupation: Dermatologist

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. [ ]

PLEASE TYPE OR PRINT IN BLACK INK

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

or FAX to:
1-800-FDA-0178

CTU 102641

FDA Form 3500 (5/93)

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