



MEDWATCH

Endo Pharmaceuticals Inc.

FDA Form Approved 07/23/1998

Case report # **Percocet2000-00341**

UP/lot report #

FDA Use Only

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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A. Patient information

1. Patient identifier: Case 269

2. Age at time of event: 35.000

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/maifunctions)

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

death 1999

life threatening

hospitalization - initial or prolonged

disability

congenital anomaly

required intervention to prevent permanent impairment/damage

other: _____

3. Date of event (m/d/yr): 1999

4. Date of this report (m/d/yr): 09/26/2000

5. Describe event or problem

Citation: Litovitz, Toby. 1999 Annual Report of the American Association of Poison Control Centers Toxic Exposure Surveillance System. American Journal of Emergency Medicine (pre-publication) 2000.

Initial notification (9/21/00):

A 35-year-old female was brought to an emergency department after her husband found her unresponsive. Her medical history included gastroparesis, G-tube insertion, and several suicide attempts with multiple drugs. Concomitant medications were Percocet (acetaminophen/oxycodone) and Soma (carisoprodol) for persistent stomach pain. She had taken 24 to 50 Tylenol PM (acetaminophen/diphenhydramine) daily for one to two weeks prior to hospitalization. She had a long history of DRUG (cont. on following page)

6. Relevant tests/Laboratory data, including dates

| Test | Value | Units | Date |
|----------------|-------|-------|------|
| Blood pressure | 60 | mmHg | |

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

Drug abuse, gastroparesis, G-tube insertion, several suicide attempts with multiple drugs.

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)

#1 Percocet Endo

#2 Soma

2. Dose, frequency & route used

#1 UNK PO

#2 UNK PO

3. Therapy dates (if unknown, give duration)

#1 Unknown

#2 Unknown

4. Diagnosis for use (indication)

#1 Pain

#2 Pain

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)

7. Exp. date (if known)

8. Event reappeared after reintroduction

#1 yes no doesn't apply

#2 yes no doesn't apply

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

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

G. All manufacturers

1. Contact office -name/address (& mailing site for devices)

Endo Pharmaceuticals Inc.
223 Wilmington West Chester Pike
Chadds Ford, PA 19317

2. Phone Number: (610) 558-9800

3. Report source (check all that apply)

foreign

study

literature

consumer

health professional

user facility

company representative

distributor

other:

4. Date received by manufacturer (m/d/yr): 09/21/2000

5. (A) NDA # 85-106

IND # _____

PLA # _____

pre-1938 yes

OTC product yes

6. Adverse event term(s)

Drug abuse

Acidosis NOS

7. Type of report (check all that apply)

5-day 15-day

10-day periodic

initial follow-up # _____

8. Mfr. report number

Percocet2000-00341

E. Initial reporter

1. Name & address

Dr. Toby Litovitz

American Assoc of Poison Control Centers

Washington DC, 20016

phone # (202) 362-7493

2. Health professional? yes no

3. Occupation

Physician

4. Initial reporter also sent report to FDA

yes no unk



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

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| | |
|-----------------|--------------------|
| Site report # | Percocet2000-00341 |
| UP/Out report # | |
| FDA Use Only | |

Section B5, Description of event/problem continuation (as necessary):

ABUSE, and when her husband found her hours earlier, he thought she was just intoxicated and did not want to disturb her. Several hours later, when he could not awaken her, he called 911. In the emergency department, she was intubated for airway protection and shock. Her blood pressure fell to 60 mmHg by palpitation. Norepinephrine was given and rapidly titrated to 25 mcg/minute. Several ampules of sodium bicarbonate were given for acidosis. Oral N-acetylcysteine treatment was initiated. Abnormal labs were AST > 7500 U/L; ALT 5775 U/L; total bilirubin 3.6 mg/dL; PTT 44.1 sec; INR 4.5; CK 907 U/L; WBC 33.9 x10³ cells/mm³; glucose 411 mg/dL; pH 7.03; pCO₂ 20 mmHg; pO₂ 422 mmHg; and O₂ saturation 97%. Acetaminophen was 11.9 ug/mL. Her urine toxicology screen was positive for THC, metoclopramide, acetaminophen, phenothiazine, and unspecified opiates. She was admitted to the ICU. Swan-Ganz catheter data was consistent with mild hypovolemic and low SVR HYPOTENSION. Cardiac output was inappropriately low for her clinical condition. The patient was transferred to a tertiary hospital for liver transplant evaluation. Additional lab results were as follows: AST 13700U/L, ALT 6140U/L, LDH >21500 U/L, total bilirubin 2.7 mg/dL, INR > 10.7, PTT > 106 sec, NH₄ 509 mcg/dL, Na 159 mEq/L, K 7.2 mEq/L, Cl 97 mEq/L, Ca 4.8 mg/dL, Mg 3.7 mEq/L, PO₄ 15.4 mg/dL, BUN 14 mg/dL, SCr 5.0 mg/dL, Hgb 5.7 g/dL, Hct 17.9%, platelets 110000/mm³, amylase 382 U/L, CK 14867 U/L, and fibrinogen 101mg/dL. The patient was not a transplant candidate due to her psychiatric history. An attempt at "medical management" was made and the family requested the discontinuation of life support systems. She died from progressive ACIDOSIS and HYPERTENSION sixteen hours after transfer.

This adverse event report was received from R.W. Johnson Pharmaceutical Research Institute who originally filed the case as a "15-day report" under Mfr Report # PRIUSA2000006669 with Tylox (oxycodone and acetaminophen) as the suspect drug. Upon receipt of follow-up information, it was found that the patient had actually taken Percocet.

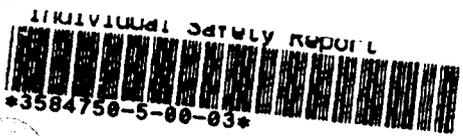
Section B6, Relevant tests/laboratory data continuation (as necessary):

| Test | Value | Units | Date |
|----------------------------|------------------------|-----------------------|------|
| AST (initial) | 7500 | U/L | |
| AST | 13700 | U/L | |
| ALT (initial) | 5775 | U/L | |
| ALT | 6140 | U/L | |
| total bilirubin (initial) | 3.6 | mg/dL | |
| total bilirubin | 2.7 | mg/dL | |
| PTT (initial) | 44.1 | sec | |
| Ammonia | 509 | mcg/dL | |
| PTT | > 106 | sec | |
| INR (initial) | 4.5 | | |
| INR | > 10.7 | | |
| Creatine kinase (initial) | 907 | U/L | |
| Creatine kinase | 14867 | U/L | |
| WBC | 33.9 x 10 ³ | cells/mm ³ | |
| glucose | 411 | mg/dL | |
| blood gas pH | 7.03 | | |
| blood gas pCO ₂ | 20 | mmHg | |
| blood gas pO ₂ | 422 | mmHg | |
| O ₂ saturation | 97% | | |
| LDH | > 21500 | U/L | |
| Na | 159 | mEq/L | |
| K | 7.2 | mEq/L | |

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| Report # | Percocet2000-00341 |
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| | |
|------------|------------|
| Cl | 97 |
| Ca | 4.8 |
| Mg | 3.7 |
| PO4 | 15.4 |
| BUN | 14 |
| SCr | 5.0 |
| HgB | 5.7 |
| Hct | 17.9% |
| platelets | 110000/mm3 |
| amylase | 382 |
| fibrinogen | 101 |

mEq/L
mg/dL
mEq/L
mg/dL
mg/dL
mg/dL
g/dL

U/L
mg/dL

Section B7, Other relevant history continuation (as necessary):

Sections C1-8, Suspect medication(s) continuation (as necessary):

| Name | Dose, frequency & route used | Therapy dates | Diagnosis for use | Lot # Exp. date | Event abated/ Event reappears |
|------------|------------------------------|---------------|-------------------|--------------------|----------------------------------|
| Tylenol PM | 50 TABSDLY PO | 2 - weeks | Pain | | NA NA |

Section C10, Concomitant medical products continuation (as necessary):

Section G8, Adverse event term(s) continuation (as necessary):

Blood pressure decreased
Hepatic failure
Hypertension NOS

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