



3584734-7-00-01

MEDWATCH

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Endo Pharmaceuticals Inc.

FDA Form 1085 Approved 07/29/1999

Med report #	Percocet2000-00340
MF/DRUG report #	

Page 1 of 2

A. Patient information

1. Patient Identifier Case 263	2. Age at time of event or Date of birth: 30.000	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight ____ lbs or ____ kgs
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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)

<input checked="" type="checkbox"/> death 1999	<input type="checkbox"/> disability
<input type="checkbox"/> life threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (month/year) 1999	4. Date of this report (month/year) 09/25/2000
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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 30-year-old female was brought to the emergency department by her husband after being sick for a week. The patient had been taking Excedrin Extra Strength (acetaminophen/ aspirin/caffeine), Percocet (acetaminophen/oxycodone), and Darvocet N-50 (acetaminophen/propoxyphene) for pain. The patient was seen by her private physician who attributed her jaundice to hepatitis. The patient was encephalopathic, vomiting blood and jaundiced in the emergency department. Her blood pressure (cont. on following page)

6. Relevant test/laboratory data, including dates

Test	Value	Units	Date
Blood glucose	30	mg/dL	

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

Pain (unspecified etiology)

C. Suspect medication(s)

1. Name (give labeled strength & manufacturer, if known)	
#1 Percocet	Endo
#2 Excedrin Extra-Strength	
2. Dose, frequency & route used	
#1 UNK PO	#1 Unknown - 1999
#2 UNK PO	#2 Unknown - 1999
3. Therapy dates (if unknown, give duration)	
#1 Unknown - 1999	
#2 Unknown - 1999	
4. Diagnosis for use (indication)	
#1 Pain	5. Event abated after use stopped or dose reduced
#2 Pain	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known)	
#1	#1
#2	#2
7. Exp. date (if known)	
#1	#1
#2	#2
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> 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)	2. Phone Number
Endo Pharmaceuticals Inc. 223 Wilmington West Chester Pike Chadds Ford, PA 19317	(610) 558-9800
3. Report source (check all that apply)	
<input type="checkbox"/> foreign <input type="checkbox"/> study <input checked="" type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other: _____	
4. Date received by manufacturer (month/year) 09/21/2000	5. (A) NDA # 85-106
6. If IND, protocol #	IND # _____
7. Type of report (check all that apply)	PLA # _____
<input type="checkbox"/> 5-day <input checked="" type="checkbox"/> 15-day <input type="checkbox"/> 10-day <input type="checkbox"/> periodic <input checked="" type="checkbox"/> initial <input type="checkbox"/> follow-up # _____	pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes
8. Adverse event term(s)	
Gastrointestinal haemorrhage NOS Hepatic failure	
9. Mfr. report number	
Percocet2000-00340	

E. Initial reporter

1. Name & address		phone #
Dr. Toby Litovitz		(202) 362-7493
American Association of Poison Control Centers Washington DC, 20016 USA		
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	Physician	DSS <input type="checkbox"/> no <input checked="" type="checkbox"/> unk

FDA

3500A Form 1085

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

SEP 29 2000

OCT 02 2000



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Endo Pharmaceuticals Inc.

FDA Product Approval 072291000	
Report #	Percocet2000-00340
UPDR report #	
FDA Use Only	

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

was 151/83 mmHg, and pulse was 112 beats per minute. She was intubated and placed on a ventilator. Her temperature was normal. Laboratory studies found a blood glucose of 30mg/dL; total bilirubin 9.5 mg/dL; AST 8200 U/L; ALT 7400U/L; acetaminophen level 13 mcg/mL; and ethanol and salicylates were both negative. An arterial blood gas pH was 7.27; pCO2 30mmHg; pO2 133 mmHg; HCO3 14 mEq/L; and O2 saturation 97%. The patient had been given dextrose to correct the hypoglycemia resulting in a blood glucose of 300 mg/dL. The poison center recommended baseline coagulation studies, administration of fresh frozen plasma, vitamin K, and N-acetylcysteine because of active gastrointestinal bleeding. As per poison center's further advice, the patient was transported for evaluation of a liver transplant. Six hours after transport, the patient had a massive GASTROINTESTINAL BLEED, developed PULMONARY EDEMA, could not be ventilated and expired. An autopsy was performed and the medical examiner listed the cause of death as HEPATIC FAILURE secondary to acetaminophen toxicity. The patient had a massive gastrointestinal bleed and pulmonary edema secondary to the hepatic failure.

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 # PRIUSA200006668 with Tylox as 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
Total bilirubin	9.5	mg/dL	
AST	8200	U/L	
ALT	7400	U/L	
acetaminophen level	13	mcg/ml	
drug levels	Negative for ethanol and salicylates		
Arterial blood gas pH	7.27		
Arterial blood gas pCO2	30	mmHg	
Arterial blood gas pO2	133	mmHg	
Arterial blood gas HCO3	14	mEq/L	
O2 saturation	97%		
Blood pressure	151/83	mmHg	
Heart rate	112 beats	per min	

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
Darvocet-N 50	UNK PO	Unknown - 1999	Pain		NA NA

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

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

Pulmonary oedema NOS
Drug abuse

SEP 29 2000

DSS

OCT 02 2000