



15-APR-1998-0192

FDA MEDICAL PRODUCTS REPORTING PROGRAM

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NDA1

Page

Individual Safety Report



\*3066285-1-00\*

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\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
FDA Use Only

A. Patient information

1. Patient identifier In confidence	2. Age at time of event: or Date of birth:	3. Sex <input 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 type="checkbox"/> death (mortality)	<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): \_\_\_\_\_

4. Date of this report (month/year): \_\_\_\_\_

5. Describe event or problem

6. Relevant tests/laboratory data, including dates

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

C. Suspect product(s)

1. Name (give labeled strength & mfr/labeler, if known)  
#3 PROPOXYPHENE WITH ACETAMINOPHEN (PARACETAMOL)  
#4 \_\_\_\_\_

2. Dose, frequency & route used  
#3 UNK, Unknown  
#4 \_\_\_\_\_

3. Therapy dates (if unknown, give duration) (month/year to best estimate)  
#3 UNK  
#4 \_\_\_\_\_

4. Diagnosis for use (indication)  
#3 PAIN  
#4 \_\_\_\_\_

5. Event abated after use stopped or dose reduced  
#3  yes  no  doesn't apply  
#4  yes  no  doesn't apply

6. Lot # (if known)  
#3 UNK  
#4 \_\_\_\_\_

7. Exp. date (if known)  
#3 UNK  
#4 \_\_\_\_\_

8. Event reappeared after reintroduction  
#3  yes  no  doesn't apply  
#4  yes  no  doesn't apply

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

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

G. All manufacturers

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

2. Phone number

3. Report source (check all that apply)

- foreign
- study
- literature
- consumer
- health professional
- user facility
- company representative
- distributor
- other: \_\_\_\_\_

4. Date received by manufacturer (month/year)

5. (A)NDA # \_\_\_\_\_  
IND # \_\_\_\_\_  
PLA # \_\_\_\_\_  
pre-1938  yes  
OTC  yes  
product  yes

6. If IND, protocol #

7. Type of report (check all that apply)

- 5-day  15-day
- 10-day  periodic
- initial  follow-up # \_\_\_\_\_

8. Adverse event term(s)

9. Mfr. report number

F. Initial reporter

1. Name, address & phone #

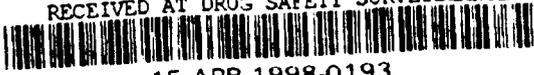
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2. Health professional?  
 yes  no

3. Occupation

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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Inuation Sheet for FDA-3500A Form

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**B. Adverse event or product problem**

**B.5 Describe event or problem (Cont...)**

reliever abuse (Darvocet, Percocet, Tylenol???)". The patient was treated with Mucomyst and attempts were made to hemodynamically stabilize her in the intensive care unit (ICU). Despite these efforts, the patient continued to deteriorate. She was removed from life support and expired on 16MAR98. The "cause of death was thought to be chronic hepatitis with unknown recent acute inciting injury." The case was referred to the medical examiner though no autopsy results are available. The patient's medical history was remarkable for seizure disorder (date of last seizure DEC94), cerebral palsy, peptic ulcer disease, asthma, arthritis, bilateral knee surgeries, colostomy, pain reliever abuse, chronic fecal impaction, chronic emesis, and allergies to penicillin, sulfa, and erythromycin. Concomitant medications included furosemide, K-dur (potassium chloride), Atrovent (ipratropium bromide), Albuterol (salbutamol), baclofen, Mylanta, and Dulcolax (bisacodyl). This case was reported by a pharmacist. FDA control no. 1701529.

**B.6 Relevant tests/laboratory data, including dates (Cont...)**

**Lab Result :**

S.No.	Test name	Test date	Test result	Normal Value
1	ALANINE AMINOTRANSFERASE	03/15/95	618	
2	ALKALINE PHOSPHATASE	03/15/95	373	
3	ASPARTATE AMINOTRANSFERASE	03/15/95	1446	
4	LACTIC DEHYDROGENASE	03/15/95	660	
5	PHENYTOIN LEVEL	03/15/95	11.3 mcg/mL	
6	TOTAL BILIRUBIN	03/15/95	2.0	

**C. Suspect medication (Cont...)**

Seq No.

C.1 Suspect medication

: 3  
: PROPOXYPHENE WITH ACETAMINOPHEN (PARACETAMOL, DEXTROPROPOXYPHENE HYDROCHLORIDE)

**C10. Concomitant medical products**

Seq No.

Concomitant Medical Product  
Therapy Duration

: 4  
: ALBUTEROL (SALBUTAMOL)  
: UNK

Seq No.

Concomitant Medical Product  
Therapy Duration

: 5  
: (BACLOFEN)  
: UNK

Seq No.

Concomitant Medical Product  
Therapy Duration

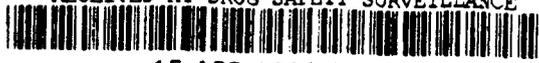
: 6  
: MYLANTA (MAGNESIUM HYDROXIDE, ALUMINIUM HYDROXIDE GEL, DRIED, DIMETICONE, ACTIVATED)  
: UNK

Seq No.

Concomitant Medical Product  
Therapy Duration

: 7  
: DULCOLAX (BISACODYL)  
: UNK

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Individual Safety Report



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10/25/95

FDA Use Only

**A. Patient information**

1. Patient identifier: UNK  
2. Age at time of event: 43 Y  
3. Sex:  female  
4. Weight: 131 lbs

**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 03/16/95  
 life-threatening  
 hospitalization - initial or prolonged  
 disability  
 congenital anomaly  
 required intervention to prevent permanent impairment/damage  
 other:

3. Date of event: 03/15/95  
4. Date of this report: 04/13/98

5. Describe event or problem:  
 A health care professional reported on 31MAR98 that a 43 year old female patient experienced confusion and a seizure leading to hospitalization, while receiving Dilantin (phenytoin sodium) 200 mg daily, Acetaminophen (paracetamol) for pain, and Propoxyphene with Acetaminophen for pain. On 15MAR95, the patient experienced confusion and a seizure while at home. She was taken to the emergency room where she was found to be unresponsive and in metabolic acidosis. "Laboratory evaluation found the patient to be in fulminant liver failure with coma thought to be due to hepatic encephalopathy." Her specific laboratory values from 15MAR98 were: Aspartate transaminase (AST) 1446, alanine transaminase (ALT) 618, lactic dehydrogenase (LDH) 660, alkaline phosphatase (Alk-phos.) 373, total bilirubin (T-bili) 2.0, lactate 13.3, phenytoin 11.3 mcg/mL, and acetaminophen < 10 mcg/mL. A Coma/drug abuse panel was positive for opiates and propoxyphene. "Acute drug intoxication was ruled out as the cause of the coma, however it was suspected that the patient might have had chronic liver failure due to pain"

6. Relevant tests/laboratory data, including dates:  
 15MAR95  
 LACTATE 13.3  
 ACETAMINOPHEN LEVEL < 10 MCG/ML  
 DRUG ABUSE PANEL POSITIVE FOR OPIATES AND PROPOXYPHENE

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.):  
 ALLERGIES TO PENICILLIN, SULFA, AND ERYTHROMYCIN  
 SEIZURE DISORDER (LAST SEIZURE 12/94)  
 CEREBRAL PALSY  
 PEPTIC ULCER DISEASE  
 ASTHMA  
 ARTHRITIS; BILATERAL KNEE SURGERIES  
 COLOSTOMY; CHRONIC FECAL IMPACTION  
 PAIN RELIEVER ABUSE  
 CHRONIC EMESIS

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known):  
 #1 DILANTIN(PHENYTOIN SODIUM)  
 #2 ACETAMINOPHEN (PARACETAMOL)

2. Dose, frequency & route used:  
 #1 200 mg (, DAILY), Unknown  
 #2 UNK, Unknown

3. Therapy dates (if unknown, give duration):  
 #1 UNK  
 #2 UNK

4. Diagnosis for use (indication):  
 #1 UNK  
 #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):  
 #1 UNK  
 #2 UNK

7. Exp. date (if known):  
 #1 UNK  
 #2 UNK

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):  
 1) (FUROSEMIDE) UNK  
 2) K-DUR (POTASSIUM CHLORIDE) UNK  
 3) ATROVENT (IPRATROPIUM BROMIDE) UNK  
 4) ALBUTEROL (SALBUTA-)

**D. All manufacturers**

1. Contact office - name/address (& mailing site for devices):  
 PARKE-DAVIS PHARM. RESEARCH, DIV W-L CO.  
 ATTN: SYLVIE TOMCZYK, M.D.  
 2800 PLYMOUTH ROAD  
 ANN ARBOR MI 48105 USA  
 ( Printing Unit )

2. Phone number: 734-622-7380

3. Report source (check all that apply):  
 foreign  
 study  
 literature  
 consumer  
 health professional  
 user facility  
 company representative  
 distributor  
 other:

4. Date received by manufacturer: 03/31/98

5. (ANDA # 84-349)  
 IND # \_\_\_\_\_  
 PLA # \_\_\_\_\_  
 pre-1938  yes  
 OTC product  yes

6. If IND, protocol #

7. Type of report (check all that apply):  
 5-day  15-day  
 10-day  periodic  
 Initial  follow-up # \_\_\_\_\_

8. Adverse event term(s):  
 1) FULMINANT LIVER FAILURE  
 2) HEPATIC ENCEPHALOPATHY  
 3) CHRONIC LIVER FAILURE  
 4) CHRONIC HEPATITIS  
 5) COMA  
 6) METABOLIC ACIDOSIS  
 7) BREAKTHROUGH SEIZURE

9. Mfr. report number: 001-0073-980167

**E. Initial reporter**

1. Name, address & phone #:  
 PHARMACIST  
 USA

2. Health professional?  
 yes  no

3. Occupation:  
 Pharmacist

4. Initial reporter also sent report to FDA:  
 yes  no  unk

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