



15-APR-1998-0194

U.S. MEDICAL PRODUCTS REPORTING PROGRAM

RESEARCH  
For use by  
doctors and  
ANDAT

Page

Individual Safety Report



\*3066286-3-00\*

FDA Use Only

**A. Patient information**

1. Patient identifier UNK	2. Age at time of event: Unk Date of birth:	3. Sex <input type="checkbox"/> female <input checked="" type="checkbox"/> male	4. Weight ____ lbs or Unk ____ 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	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input checked="" type="checkbox"/> hospitalization - initial or prolonged	<input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other: _____

3. Date of event (month/day/yr): 09/08/94

4. Date of this report (month/day/yr): 04/13/98

5. Describe event or problem

A consumer reported on 31MAR98 that an adult male experienced liver damage and liver failure leading to a liver transplant while receiving Dilantin (phenytoin sodium) (unknown dosage), orally and Extra Strength Tylenol (paracetamol) (unknown dosage), orally. He started taking phenytoin in 1977 for seizures. On approximately 05SEP94 he began taking paracetamol. On 08SEP94, the patient was taken to an emergency room and was diagnosed with liver failure. Paracetamol was discontinued. On 09SEP94, he was transferred to another hospital. He received a liver transplant on 15SEP94. No further information was provided. The patient has no known drug allergies. This case was reported by a consumer's representative via McNeil Consumer Products Company. FDA contact no. 1803371.

6. Relevant tests/laboratory data, including dates

UNK

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

NO KNOWN DRUG ALLERGIES

**C. Suspect ingredient(s)**

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

#1 DILANTIN (PHENYTOIN SODIUM)

#2 EXTRA STRENGTH TYLENOL (PARACETAMOL)

2. Dose, frequency & route used

#1 UNK, Per oral

#2 UNK, Per oral

3. Therapy dates (if unknown, give duration)

#1 1977 - UNK

#2 09/05/94 - 09/08/94

4. Diagnosis for use (indication)

#1 SEIZURES

#2 UNK

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) UNK

**D. All manufacturers**

1. Contact office - name/address (& mfg 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 (month/day/yr)

03/31/98

5. (ANDA # 84-349)

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)

1) LIVER DAMAGE

2) LIVER FAILURE

9. Mfr. report number

001-0073-980168

**E. Initial reporter**

1. Name, address & phone #

CONSUMER  
USA

2. Health professional?

yes  no

3. Occupation

N/A

4. Initial reporter also sent report to FDA

yes  no  unk

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