



3280888-0-00-01

Mfr report #	PRIUSA1999001947
UT/Dist report #	
FDA Use Only	

A. Patient information

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

3. Date of event (mo/day/yr) 01/??/98

4. Date of this report (mo/day/yr) 06/04/99

5. Describe event or problem

Report from son of a 62-year-old male on treatment with acetaminophen with codeine #4 TID, oxycodone with acetaminophen TID and propoxyphene napsylate with acetaminophen BID (doses unspecified) for 8.5 years for neuropathy of the feet. In Jan-98 the patient underwent stomach surgery for an unspecified reason, during which time cirrhosis of the liver was found, and stomach surgery was not performed. Medications were discontinued at this time. Subsequently, the patient has had heart surgery for blood clots and fluid drainage from lungs, liver and spleen.

6. Relevant test/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.)

No Pat Profiles Rptd
Unknown

C. Suspect medication(s)

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

#1 **TYLENOL W/CODEINE NO. 4 (tablet) (ACETAMINOPHEN/CODEINE)**

#2 **TYLOX (capsule) (OXYCODONE/ACETAMINOPHEN)**

2. Dose, frequency & route used

#1 unk, 3 in 1 daily, oral

#2 unk, 3 in 1 daily, oral

3. Therapy dates (if unknown, give duration) (from/to or best estimate)

#1 07/??/89 - 01/??/98

#2 07/??/89 - 01/??/98

4. Diagnosis for use (indication)

#1 **UNSPECIFIED IDIOPATHIC PERIPHERAL NEUROPATHY**

#2 **UNSPECIFIED IDIOPATHIC PERIPHERAL NEUROPATHY**

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

#2

7. Exp. date (if known)

#1

#2

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)

No Concomitant Products Reported

G. All manufacturers

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

R.W. JOHNSON PHARM. RES. INST. USA
DIV. OF ORTHO PHARMACEUTICAL CORP.
920 U.S. Route 202
P.O. Box 300
Raritan NJ 08869
USA
(Informing Unit)

2. Phone number 908-704-4504

3. Report source (check all that apply)

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

4. Date received by manufacturer (mo/day/yr) 05/28/99

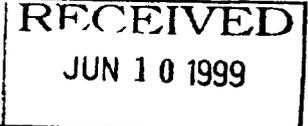
5. (A)NDA # 85-055

IND # _____
PLA # _____

pre-1938 yes
OTC product yes

8. Adverse event term(s)

1) HEPATIC CIRRHOSIS



9. Mfr. report number
PRIUSA1999001947

F. Initial reporter

1. Name, address & phone #
Consumer
[Redacted]
USA

DSS

JUN 11 1999

2. Health professional? yes no

3. Occupation Unknown

ADVERSE EVENT REPORTING SYSTEM

4. 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.



Mfr report # PRIUSA1999001947

UF/Dist report #

FDA Use Only

FDA MEDICAL PRODUCTS REPORTING SYSTEM

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A. Patient information

1. Patient identifier	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 _____ (mo/day/yr)	<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 (mo/day/yr)

4. Date of this report (mo/day/yr)

5. Describe event or problem

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)
#3 DARVOCET (DARVOCET)
#4 _____

2. Dose, frequency & route used
#3 unk, 2 in 1 daily, oral
#4 _____

3. Therapy dates (if unknown, give duration from/to or best estimate)
#3 07/??/89 - 01/??/98
#4 _____

4. Diagnosis for use (indication)
#3 UNSPECIFIED IDIOPATHIC PERIPHERAL NEUROPATHY
#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 _____
#4 _____

7. Exp. date (if known)
#3 _____
#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)
#3 _____
#4 _____

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

G. All manufacturers

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

2. Phone number

3. Report source (check all that apply)

<input type="checkbox"/> foreign
<input type="checkbox"/> study
<input type="checkbox"/> literature
<input type="checkbox"/> consumer
<input 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 (mo/day/yr)

5. (A)NDA # _____
IND # _____
PLA # _____

6. If IND, protocol # _____

7. Type of report (check all that apply)

<input type="checkbox"/> 5-day	<input type="checkbox"/> 15-day
<input type="checkbox"/> 10-day	<input type="checkbox"/> periodic
<input type="checkbox"/> initial	<input type="checkbox"/> follow-up # _____

8. Adverse event term(s)

9. Mfr. report number

RECEIVED
JUN 10 1999
BY: _____

E. Initial reporter

1. Name, address & phone #

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.

ADVERSE EVENT REPORTING SYSTEM



3280888-0-00-03

Continuation Sheet for FDA-3500A Form

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Mfr. report # : PRIUSA1999001947

Date of this report : 06/04/99

C. Suspect medication (Cont...)

Seq No.
C.I Suspect medication
Approval information
ANDA #

: 2
: TYLOX (capsule) (OXYCODONE/ACETAMINOPHEN)
: 88-790

RECEIVED
JUN 10 1999
BY:
DSS

JUN 11 1999

ADVERSE EVENT REPORTING SYSTEM