



3300514-1-00-01

ON PHARM. RES. INST. USA
For use by user-facilities,
distributors and manufacturers for
MANDATORY reporting

Approved by FDA on 06/25/95

Mfr. report #	PR1USA1999003044
L7/Date report #	
FDA Lab. Dist.	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page 1 of 2

A. Patient information			
1. Patient identifier [redacted]	2. Age at time of event: or Date of birth: [redacted]	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 170 lbs or [redacted] kg
B. Adverse event or product problem			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g., defects/malfunctions)			
2. Outcomes attributed to adverse event (check all that apply): <input type="checkbox"/> death <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other:			
3. Date of event (m/d/yyyy) 06/27/99	4. Date of this report (m/d/yyyy) 07/06/99		
5. Describe event or problem <p>Report via McNeil Consumer Healthcare (Mfr. number 1199389A) from a 20-year-old female consumer who had taken staggering doses of 1000 mg of extra strength acetaminophen with codeine #3 every 4 hours for tonsillectomy pain for 7 days. In the early morning of 27-Jun-99 the patient experienced abdominal pain, trouble breathing and could not sleep approximately one hour after ingesting products. The patient was advised by the poison control center to seek medical attention. She was seen in the emergency room where the physician noted her liver felt enlarged on physical examination. The patient was given IV fluids and a single dose of acetylcysteine. Results of blood work were normal and the patient was released home. Extra strength acetaminophen and acetaminophen with codeine #3 were discontinued. Later the same day the patient experienced vomiting which resolved several hours later. On 28-Jun-99, the abdominal pain had not yet resolved.</p>			
6. Relevant tests/laboratory data, including dates <p>In emergency room physical examination revealed enlarged liver, blood work normal</p>			
7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.) <p>No Pat Profiles Rptd Unknown</p>			

DSS

JUL 12 1999

JUL 9 1999

ADVERSE EVENT REPORTING SYSTEM

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

3500A Facsimile

C. Suspect medication(s)			
1. Name (give labeled strength & mfr/labeler, if known) #1 TYLENOL WITH CODEINE (elixir) (ACETAMINOPHEN/CODEINE) #2 TYLENOL (PARACETAMOL) (Cont.)			
2. Dose, frequency & route used #1 3 tsp, 4 hour(s), oral #2 1000 mg, 4 hour(s), oral		3. Therapy dates (if unknown, give duration) (months or best estimate) #1 06/21/99 - 06/27/99 #2 06/21/99 - 06/27/99	
4. Diagnosis for use (indication) #1 PAIN #2 PAIN		5. Event abated after use stopped or dose reduced #1 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply #2 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply unknown	
6. Lot # (if known) #1 #2		7. Exp. date (if known) #1 #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 type="checkbox"/> doesn't apply			
9. NDC # - for product problems only (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event) 1) AMOXICILLIN (AMOXICILLIN) (Cont.)			
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	
4. Date received by manufacturer (m/d/yyyy) 06/28/99		3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input checked="" 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:	
6. If IND, protocol #		5. (A)INDA # 85-057 IND # PLA # pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes	
7. Type of report (check all that apply) <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 #		8. Adverse event term(s) 1) THERAPEUTIC RESPONSE INCREASED 2) HEPATOMEGALY 3) DYSPNOEA 4) INSOMNIA 5) ABDOMINAL PAIN 6) VOMITING	
9. Mfr. report number PR1USA1999003044			
F. Initial reporter			
1. Name, address & phone # McNeil Consumer Healthcare 7050 Camp Hill Road Fort Washington, PA 19034 USA Phone # : (215) 273-7900			
2. Health professional? <input type="checkbox"/> yes <input type="checkbox"/> no		3. Occupation UNK	
4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk			



3300514-1-00-02

Karitan NJ 08869
USA

Continuation Sheet for FDA-3500A Form

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Mfr. report # : PRIUSA1999003044

Date of this report : 07/06/99

C. Suspect medication (Cont...)

Seq No.
C.I Suspect medication

: 1
: TYLENOL WITH CODEINE (elixir) (ACETAMINOPHEN/CODEINE)

C10. Concomitant medical products

Seq No.
Concomitant Medical Product
Dose, frequency & route used

: 1
: AMOXICILLIN (AMOXICILLIN)
: 1) unk, unknown

DSS

JUL 12 1999

ADVERSE EVENT REPORTING SYSTEM

JUL 9 1999