

INDIVIDUAL SAFETY REPORT



\*3297956-X-00-01\*

INDIVIDUAL SAFETY REPORTING PROGRAM



Consumer Healthcare  
McNeil Consumer Healthcare  
Fort Washington, PA 19034-2299

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Approved by FDA on 11/15/93

Mfr report #
UDI/Dir report #
FOA use only

**A. Patient information**

1. Patient identifier	2. Age at time of event: 20 yrs or Date of birth	3. Sex (X) female ( ) male	4. Weight 170 lbs or kgs
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**B. Adverse event or product problem**

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)

2. Outcomes attributed to adverse event (check all that apply)

( ) death (mo/day/yr)  
( ) life-threatening  
( ) hospitalization - initial or prolonged

( ) disability  
( ) congenital anomaly  
(X) required intervention to prevent permanent impairment/damage  
( ) other:

3. Date of event (mo/day/yr) 6/27/99

4. Date of this report (mo/day/yr) 06/28/99

5. Describe event or problem

Consumer report of OVERDOSE allegedly associated with the use of Extra Strength TYLENOL acetaminophen Liquid. A 20 yo female reported taking staggered doses of 1000 mg of Extra Strength TYLENOL liquid q4hrs & 3 to 5 teaspoonfuls q4hrs of TYLENOL #3 for tonsillectomy pain for 7 days. In the early morning on 6/27/99, consumer reportedly experienced INSOMNIA (couldn't sleep), ABDOMINAL PAIN, & DYSPNEA (trouble breathing) approximately 1 hour after ingesting products. Consumer reported calling poison control center & was advised to seek medical attention. Consumer went to ER where physician noted that her liver felt enlarged (HEPATOMEGALY) on physical exam. Consumer was given IV fluids and a single dose of MUCOMYST. According to consumer, results of blood work were all normal & acetaminophen level was 11. Consumer was released to home. Consumer reported discontinuing use of both products following ER visit. Later on 6/27/99, consumer experienced VOMITING which resolved several hours later. On 6/28/99, consumer reported that abdominal (See Sect 87)

6. Relevant tests/laboratory data, including dates

In ER: physical exam reportedly revealed that liver was enlarged; acetaminophen level=11; all blood work was reportedly normal

**DSS**  
**JUL 07 1999**

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

tonsillectomy 6/21/99; NKDA

Sect 85 cont: pain had not yet recovered

**C. Suspect medication(s)**

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

#1 Extra Strength TYLENOL Liquid  
#2 TYLENOL #3 Elixir

2. Dose, frequency & route used

#1 1000 mg, q4hrs, po  
#2 3-5 teaspoonfuls, q4hrs, po

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

#1 6/21/99-6/27/99; 7 days  
#2 6/21/99-6/27/99; 7 days

4. Diagnosis for use (indication)

#1 tonsillectomy pain  
#2 tonsillectomy pain

5. Event abated after use stopped or dose reduced

#1 ( ) Yes ( ) No (X) N/A  
#2 ( ) Yes ( ) No (X) N/A

6. Lot # (if known)

#1 unknown  
#2 unknown

7. Exp. date (if known)

#1 unknown  
#2 unknown

8. Event reappeared after reintroduction

#1 ( ) Yes ( ) No (X) N/A  
#2 ( ) Yes ( ) No (X) N/A

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

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

amoxicillin

**G. All manufacturers**

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

McNeil Consumer Healthcare  
Medical Affairs  
7050 Camp Hill Road  
Ft. Washington, PA 19034

2. Phone number

215-273-7820

3. Report source (check all that apply)

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

4. Date received by manufacturer (mo/day/yr) 06/28/99

5. (A) NDA # 19-872  
IND #  
PLA #  
pre-1938 ( ) Yes  
OTC product (X) Yes

6. If IND, protocol #

7. Type of report (check all that apply)

( ) 5-day (X) 15-day  
( ) 10-day ( ) periodic  
(X) Initial ( ) follow-up #

8. Adverse event term(s)

OVERDOSE INSOMNIA  
PAIN ABDOMINAL DYSPNEA  
HEPATOMEGALY VOMITING

9. Mfr. report number

1199389A

**E. Initial reporter**

1. Name, address & phone #

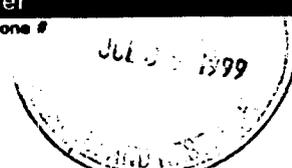
2. Health professional?

( ) 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 professional, user facility, distributor, manufacturer or product caused or contributed to the event.