



3594879-3-00-01*

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Approved by FDA on 11/18/93

Mfr report #
UP/Dist report #
FDA use only

Page ___ of ___

A. Patient information

1. Patient identifier unknown in confidence	2. Age at time of event: or 27 yrs Date of birth:	3. Sex (X) female () male	4. Weight unk lbs or kgs
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C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known) #1 unspecified acetaminophen 325 mg tablet #2 cocaine		3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 4 days prior to admission #2 3 days prior to admission	
2. Dose, frequency & route used #1 32.5 g over 2 days, po #2 unknown dose		4. Diagnosis for use (indication) #1 toothache #2 unknown	
5. Event abated after use stopped or dose reduced #1 (X) Yes () No () N/A		6. Event reappeared after reintroduction #1 () Yes () No (X) N/A	
8. Lot # (if known) #1 Unknown #2 unknown		7. Exp. date (if known) #1 Unknown #2 unknown	
9. NDC # - for product problems only (if known)		10. Concomitant medical products and therapy dates (exclude treatment of event) unknown	

B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)	
2. Outcome attributed to adverse event (check all that apply)	
() death (m/d/yr)	() disability
() life-threatening	() congenital anomaly
(X) hospitalization - initial or prolonged	() required intervention to prevent permanent impairment/damage
(X) other: recovered	
3. Date of event (m/d/yr) unknown	4. Date of this report (m/d/yr) 10/10/00

5. Describe event or problem

Abstract #166 from the North American Congress of Clinical Toxicology, Annual Meeting 2000 of a 27 year-old female, 30 weeks pregnant, who reportedly ingested 100 x 325 mg tablets (OVERDOSE) of APAP over a 2 day period for a toothache. Patient presented 4 days post-ingestion. She reported no APAP use for the 2 days immediately prior to admission, but did report cocaine use. Initial laboratory abnormalities included: INR=8 (BLEEDING TIME INCREASED), AST=11316 U/L, LT=3440 U/L (LIVER FUNCTION TESTS ABNORMAL), APAP=10 Cr=2.1 mg/dL (CREATININE INCREASED). At presentation, pt was in active labor (ABNORMAL LABOR) & was taken for an immediate Cesarean section. The neonate (Mfr. Report No. 1429743A), born at 30 weeks gestation, 1.5 kg, was admitted to the NICU. The child was treated with oral NAC. Mother and child recovered without further complication.

Addl info rec'd 10/6/00: Written comments from physician indicate that the mother had used cocaine 3 days prior to admission not 2 as previously reported. (See Sect B7)

6. Relevant tests/laboratory data, including dates 4 days post-ingestion: INR=8, AST=11316 U/L, ALT=3440U/L, APAP=10 ug/mL, Cr=2.1 mg/dL

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
30 weeks pregnant; admits cocaine use prior to admission

(Sect B5 cont): Patients were treated at an outside facility. Physician was consulted via telephone. As such, physician does not have access to patient records.

G. All manufacturers

1. Contact office - name/address (& mfring site for devices) McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034		2. Phone number 215-273-7303
4. Date received by manufacturer (m/d/yr) 10/06/00		3. Report source (check all that apply) () foreign () study (X) literature () consumer (X) health professional () user facility () company representative () distributor () other:
5. (A) NDA # 19-872 IND # PLA # pre-1938 () Yes OTC product (X) Yes	6. Adverse event term(s) OVERDOSE BLEED TIME INC LIVER FUNC ABNO CREATININE INC LABOR ABNORMAL	
7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic () initial (X) follow-up # 1	8. Mfr. report number 1429700A	

E. Initial reporter

1. Name, address & phone # A.N. Sharma, MD New York City Poison Control Center 455 First Avenue New York, NY 10016		DSS OCT 16 2000	
2. Health professional? (X) Yes () No	3. Occupation physician	4. Initial reporter also sent report to FDA () Yes (X) No () No	