



3594880-X-00-01

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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

Mfr report # Approved by FDA on 11/15/99
UF/Dist report #
FDA use only

Page ___ of ___

A. Patient information

1. Patient Identifier unknown In confidence	2. Age at time of event: or neonate Date of birth:	3. Sex () female (X) male	4. Weight lbs or 1.5 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)	() disability
() life-threatening	() congenital anomaly
(X) hospitalization - initial or prolonged	(X) required intervention to prevent permanent impairment/damage
	(X) other: recovered

3. Date of event (mo/day/yr) unknown	4. Date of this report (mo/day/yr) 10/10/00
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5. Describe event or problem

Abstract #166 from the North American Congress of Clinical Toxicology, Annual Meeting 2000 of a 27 year-old female (Mfr. Report No. 1429700A), 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. presentation, pt was in active labor & was taken for an immediate Cesarean section. The neonate, born at 30 weeks, gestation (PREMATURE BIRTH), 1.5 kg, was admitted to the NICU. His initial cord blood analysis revealed: APAP=7 ug/mL, AST=229 U/L (SGOT INCREASED), & Cr=2.4 mg/dL (CREATININE INCREASED). The decision was made to treat with NAC, but the ideal route of administration was debated. Neonate was maintained NPO due to risk of necrotizing enterocolitis (NEC) and his 24-hr IV fluid intake was limited to 80mL. Fluid restrictions made IV NAC difficult to administer. Ultimately, child was tx'd w/ oral (See Sect B7)

6. Relevant tests/laboratory data, including dates

initial cord blood analysis: APAP=7 ug/mL, AST=229 U/L, Cr=2.4 mg/dL

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

mother was 30 weeks pregnant (Sect B5 cont) NAC using the standard US protocol & tolerated all 18 doses without any evidence of NEC. Mother & child recovered without further complication.

add info rec'd 10/6/00: Written comments from physician indicate that the mother had used cocaine 3 (See Sect C10)

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration) from/to (or best estimate)	
#1 unspecified acetaminophen 325 mg tablet		#1 4 days prior to admission	
#2 cocaine		#2 3 days prior to admission	
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced	
#1 unknown dose		#1 (X) Yes () No () N/A	
#2 unknown dose		#2 (X) Yes () No () N/A	
4. Diagnosis for use (indication)		8. Event reappeared after reintroduction	
#1 maternal ingestion		#1 () Yes () No (X) N/A	
#2 maternal use		#2 () Yes () No (X) N/A	
6. Lot # (if known)	7. Exp. date (if known)		
#1 Unknown	#1 Unknown		
#2 unknown	#2 unknown		
9. NDC # - for product problems only (if known)			
10. Concomitant medical products and therapy dates (exclude treatment of event) unknown (Sect B7 cont) days prior to admission not 2 as previously reported. 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)	2. Phone number	3. Report source (check all that apply)
McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034	215-273-7303	
4. Date received by manufacturer (mo/day/yr) 10/06/00	5. (A) NDA # 19-872 IND # PLA # pre-1938 () Yes OTC product (X) Yes	() foreign () study (X) literature () consumer () health professional (X) professional () user facility () company representative () distributor () other:
6. If IND, protocol #	8. Adverse event term(s) OVERDOSE BIRTH PREMATURE SGOT INCREASED CREATININE INC	
7. Type of report (check all that apply) () 5-day (X) 15-day () 10-day () periodic () Initial (X) follow-up # 1	9. Mfr. report number 1429743A	

E. Initial reporter

1. Name, address & phone #	DSS	
Center	OCT 16 2000	
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
(X) Yes () No	physician	() Yes (X) No () No



Facsimile Form 3500A

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

OCT 13 2000