



THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

Page of

**A. Patient information**

1. Patient identifier unknown In confidence	2. Age at time of event: unknown or Date of birth:	3. Sex ( ) female ( ) male	4. Weight unk lbs or kgs
---	---	----------------------------------	-----------------------------------

**C. Suspect medication(s)**

1. Name (give labeled strength & mfr/labeler, if known) #1 unspecified acetaminophen product #2		3. Therapy dates (if unknown, give duration from/to for best estimate) #1 unknown dates or duration #2	
2. Dose, frequency & route used #1 unknown dose, po #2		4. Diagnosis for use (indication) #1 unknown #2	
5. Event abated after use stopped or dose reduced #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A		6. Lot # (if known) #1 Unknown #2	
7. Exp. date (if known) #1 Unknown #2		8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No ( ) N/A	
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. Outcomes attributed to adverse event (check all that apply)	
( ) death (mo/day/yr)	( ) disability
( ) life-threatening	( ) congenital anomaly
(X) hospitalization - initial or prolonged	( ) required intervention to prevent permanent impairment/damage
( ) other:	
3. Date of event unknown (mo/day/yr)	4. Date of this report 10/19/00 (mo/day/yr)

5. Describe event or problem

Literature report (Ann Emerg Med 2000;36(4):S83) of a prospective, randomized multicenter study open to all suspected acute or chronic acetaminophen overdoses (OVERDOSE). Specific doses were not provided. The study was a comparison between continuous and intermittent intravenous N-acetylcysteine 48-hour protocols. The study was designed to determine whether an intravenous NAC protocol provides the same efficacy while decreasing adverse or iatrogenic effects. Patients with asthma or COPD were excluded. Of 18 patients enrolled, 17 completed the protocols. The other patient arrived in hepatorenal failure (HEPATORENAL SYNDROME) and was transferred to a transplant center. No further information provided on the clinical course of this case. Hepatotoxicity developed transiently in all 4 "high-risk" patients. None occurred in patients with "possible/probable" risk or those with chronic/unknown times of ingestion. No deaths or iatrogenic dosing occurred. There were no reports of anaphylactoid reaction. (See Sect B6)

**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 (mo/day/yr) 10/19/00		3. Report source (check all that apply) ( ) foreign ( ) study (X) literature ( ) consumer  (X) health professional ( ) user facility  ( ) company representative ( ) distributor ( ) other:
6. If IND, protocol #		
7. Type of report (check all that apply) ( ) 5-day (X) 15-day ( ) 10-day ( ) periodic (X) Initial ( ) follow-up #		
5. (A) NDA # 19-872 IND # PLA # pre-1938 ( ) Yes  OTC product (X) Yes		8. Adverse event term(s) OVERDOSE      HEPATORENAL SYN
9. Mfr. report number 1447652A		

8. Relevant tests/laboratory data, including dates

unknown  
(Sect B5 cont): Authors conclude that a continuous intravenous NAC protocol appears to be a safe and effective alternative to the 48-hour intravenous intermittent regimen.

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

unknown

**E. Initial reporter**

1. Name, address & phone # T. Dougherty Cape Coral Hospital 636 Del Prado Boulevard Cape Coral, FL 33990-2695		4. Initial reporter also sent report to FDA ( ) Yes ( ) No (X) Unk	
2. Health professional? (X) Yes ( ) No		3. Occupation unknown	

DSS  
OCT 27 2000

OCT 26 2000