



**McNeil**  
 Consumer Healthcare  
 McNeil Consumer Healthcare  
 Fort Washington, PA 19034-2299  
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Approved by FDA on 11/15/93  
 Mfr report #  
 LP/Dist report #  
 FDA use only

**A. Patient information**      **C. Suspect medication(s)**

1. Patient identifier  In confidence	2. Age at time of event: 71 yrs or Date of birth: 08/18/1928	3. Sex (X) female  ( ) male	4. Weight unk lbs or kgs
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1. Name (give labeled strength & mfr/labeler, if known) #1 unspecified <b>TYLENOL</b> product #2 <b>ISOPTIN</b> SR	3. Therapy dates (if unknown, give duration) from/to (or best estimate) #1 unknown date to ?? 12/99 #2 started on 12/2/99
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**B. Adverse event or product problem**

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)	( ) disability
2. Outcomes attributed to adverse event (check all that apply)	( ) congenital anomaly
( ) death (mo/day/yr)	( ) required intervention to prevent permanent impairment/damage
(x) life-threatening	(x) other: recovered
(x) hospitalization - initial or prolonged	

2. Dose, frequency & route used #1 7-8 tablets/day, po #2 120 mg, qd, po	4. Diagnosis for use (indication) #1 low back pain (LBP) #2 hypertension
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3. Date of event (mo/day/yr) 12/15/1999	4. Date of this report (mo/day/yr) 04/04/00
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6. Lot # (if known) #1 unknown #2 unknown	7. Exp. date (if known) #1 unknown #2 unknown	5. Event abated after use stopped or dose reduced #1 (X) Yes ( ) No ( ) N/A #2 (X) Yes ( ) No ( ) N/A
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5. Describe event or problem  
 Clinical investigator report rec'd via other mfr (Mfr. Control No. USA012050) of elevated LFTs & ATRIAL FIBRILLATION allegedly associated w/use of unspecified **TYLENOL** acetaminophen product, **ISOPTIN** SR & **PERCOCET** in 71 y/o F. Subject w/hx of HTN & CAD was enrolled in INVEST study (opened label post-marketing). Addl info rec'd 4/6/00: Med rec indicate pt referred to ED by PCP after routine INR check revealed elevated INR & LFTs. LFT levels c/w HEPATIC FAILURE secondary to toxin. Pt admitted taking approx 7 **PERCOCET** & approx 7-8 unspecified **TYLENOL** tabs QD for severe pain. GI consult indicated pt's clinical picture c/w APAP OVERDOSE. On 12/15/99, pt admitted to MICU for tx w/IV **MUCOMYST** & observation for GI bleed. Pt developed Afib & was tx'd w/diltiazem & digoxin. On 12/18/99, pt developed fever, ABG's indicated CO2 retention & HYPOXIA. Blood & urine cx revealed urosepsis (SEPSIS);tx'd w/ciprofloxacin. Pt had reduced mental status & developed hepatic encephalopathy (ACUTE BRAIN SYNDROME). On 12/22/99, pt converted back to (See Sect B7)

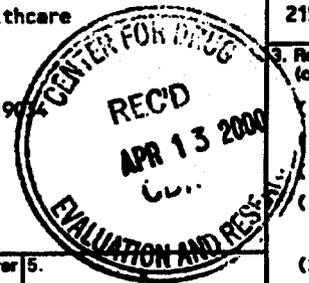
8. Event reappeared after reintroduction #1 ( ) Yes ( ) No (X) N/A #2 ( ) Yes ( ) No (X) N/A
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9. NDC # - for product problems only (if known) - -	10. Concomitant medical products and therapy dates (exclude treatment of event) potassium, ASA, ORNADE, albuterol inhaler, AEROBID & VALIUM (diazepam) (Sect C1 cont): #3 <b>PERCOCET</b> , 6 tabs/day, po for approx 1 yr for LBP;(Sect B6 cont):cx also citrobacter;12/27/99 colonoscopy=no active bleeding& sigmoid polyps.
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6. Relevant tests/laboratory data, including dates  
 ED:INR greater than 20,HCT=20,MCV=56,RDW=24;12/15/99:AST=2000IU/L range, PT=8sec;unspecified date:CKR=RT pleural effusion & bilateral pulmonary edema,EKG=atrial flutter;  
 12/18/99 blood & urine cx=enterobacter, urine (See Sect C10)  
 APR 14 2000

**G. All manufacturers**

1. Contact office - name/address ( & mfring site for devices) McNeil Consumer Healthcare Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19074	2. Phone number 215-273-7303
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4. Date received by manufacturer (mo/day/yr) 04/03/00	5. (A) NDA # 19-872 IND # PLA # pre-1938 ( ) Yes OTC product (X) Yes	3. Report source (check all that apply) ( ) foreign ( ) study ( ) literature ( ) consumer (x) health professional ( ) user facility ( ) company representative ( ) distributor (x) other: manufact
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7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)  
 HTN, CAD, LBP due to osteoporosis, hypercholesterolemia, AAA (s/p graft 10/95), DVT's, recurrent PE & LSC;(Sect B5 cont): rapid Afib. SR restored after metoprolol. On 12/27/99, pt had colonoscopy & EGD;no obvious sources of bleed.Pt improved & d/c from hosp on 12/28/99. Final dx:acute hepatic failure, urosepsis, RF (APNEA) & s/p GI HEMORRAGE (GI bleed).

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) FIBRILLAT ATR LIVER FAILURE OVERDOSE HYPOXIA SEPSIS BRAIN SYND ACUT APNEA HEMORRAGE GI
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**E. Initial reporter**

1. Name, address & phone # Rossano Cornejo, MD Knoll Pharmaceutical Company 3000 Continental Drive - North Mount Olive, NJ 07828-1234	(973) 426-2600
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2. Health professional? (X) Yes ( ) No	3. Occupation physician	4. Initial reporter also sent report to FDA (X) Yes ( ) No ( ) Unk
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Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or