

Individual Safety Report



3649878-3-00-01

Form Approved: OMB No. 0910-G291
FDA Use Only

MEDWATCH

for VOLUNTARY reporting
by health professionals of adverse
events and product problems

Triage unit
sequence # **135679**

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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A. PATIENT INFORMATION			
1. Patient identifier	2. Age at event 44 YO or _____ DOB: _____	3. Sex [] female [X] male	4. Weight or lbs 61.3 kgs
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. [X] Adverse Event and/or [] Product problem			
2. Outcomes attrib. to event [] disability [] death [] congen anomaly (mo/day/yy) [X] required intervention to [] life-threatening prevent perm impair/damage [X] hospitalization - [] other: initial or prolonged			
3. Date of event 03/03/2000		4. Date of this Rept 01/10/2001	
5. Describe event or problem 44 yo male patient admitted obtunded secondary to acetaminophen overdose due to taking Vicodin for back pain. This could have been a purposeful overdose and would not warrant this report. He received acetylcysteine but upon discharge his LFTs remained elevated.			
6. Relevant tests/laboratory data, including dates APAP 169 (range 10-20), elevated LFTs - ALT 429 (7-56), Alk Phos 208 (38-126), AST 115 (7-4C)			
7. Other relevant history, including preexist. med. conditions Multiple surgeries secondary to chronic back pain, GERD			

C. SUSPECT MEDICATION(S)		
1. Name (give labeled strength & mfr/labeler, if known): #1 Vicodin #		
2. Dose, frequency & route #1 UNK #	3. Therapy dates (if unk, give dur) #1 #	
4. Diagnosis for use (indication) #1 chronic back pain #		5. Event abated after use stopped or dose reduced #1 [] yes [X] no [] N/A # [] yes [] no [] N/A
6. Lot # (if known) #1 #	7. Exp. Date #1 #	8. Event reappeared after reintroduction #1 [] yes [] no [] N/A # [] yes [] no [] N/A
9. NDC # for prod problems only #1 #		
10. Concomitant medical products and therapy dates		

D. SUSPECT MEDICAL DEVICE			
1. Brand name			
2. Type of device			
3. Manufacturer name & address		4. Operator of Dev. [] Hlth Profes. [] lay user/pat. [] other:	
6. Model#		5. Expiration Date	
catalog#		7. If implanted, give date	
serial#		8. If removed, give date	
lot#		9. Device available for evaluation? (Do not send to FDA) [] yes [] no [] returned to mfr or	
other#		10. Concomitant medical products and therapy dates	

E. INITIAL REPORTER			
1. Name, address & phone # 			
2. Health profess.? [X] yes [] no	3. Occupation Pharmacist	4. Also reported to [] manufacturer [] user facility [] distributor	
5. If you do NOT want your identity disclosed to the Mfr, place an 'X' in box []			

MED INFO ASSOC Mail MedWatch or FAX to:
Facsimile to: 560C Fishers Lane 1-800-FDA-0178
Form 3500 Rockville, MD 20852-9787
Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the ev

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