



MEDWATCH

SEARLE Drug Experience Report

U.S. REPORTING

Approved by FDA on September 17, 1993

Searle Research and Development

Mfr report #	990811-SK077
UF/Date report #	
FDA Use Only	

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

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A. Patient information

1. Patient identifier	2. Age at time of event: 61 Yrs or Date of birth:	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 262 lbs or kgs
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B. Adverse event or product problem

1. Adverse event and/or Product problem (e.g., defects/mafunctions)

2. Outcomes attributed to adverse event (check all that apply)

<input type="checkbox"/> death (mortality)	<input type="checkbox"/> disability
<input type="checkbox"/> life-threatening	<input type="checkbox"/> congenital anomaly
<input type="checkbox"/> hospitalization - initial or prolonged	<input type="checkbox"/> required intervention to prevent permanent impairment/damage
	<input type="checkbox"/> other:

3. Date of event (mortality)	AUG 5 1999	4. Date of this report (mortality)	SEP 27 1999
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5. Describe event or problem
On Aug-09-99, this family practitioner reports that a 61-year-old female patient, has been taking Nicobid up to 2 capsules per day since 1996 for hypercholesterolemia, and Tylenol #3 up to 6 tablets per day for pain, and she has been using acetaminophen 500 mg between 2 to 4 doses per day for pain. She has a past medical history of an elevated GGT of 102 on Mar-29-99. On Jul-09-99, she started taking Arthrotec (diclofenac/misoprostol) 75 mg twice daily, for arthritis. On Aug-05-99, she had elevated liver enzymes, specifically her SGOT had increased to 53 from 27 on Mar-26-99 (normal is 11-38), her SGPT increased to 48 from 21 on Mar-26-99 (normal is 11-43), GGT had increased to 132 from 102 on Mar-29-99 (normal is 5-27). The physician suspects that the Nicobid and the acetaminophen may be causing the elevated liver enzymes. She has been using less acetaminophen since starting the Arthrotec because the Arthrotec is helping her pain.

6. Relevant test/laboratory data, including dates

Aug-05-99 patient had elevated liver enzymes:

	Mar-99	Aug-99
SGOT	27	53
SGPT	21	48
GGT	102	132

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
CONCOMITANT ILLNESSES: HYPERTENSION NOS; HYPOTHYROIDISM NOS; DIABETES MELLITUS; ADE MED/BIOL SUBST NOS; ARTHROPATHY NOS
Hypertension since 1980's
Mixed collagen disease - late 80's/early 90's - some physicians think it is Lupus, others don't
Hypothyroidism since 1996
Reduplication of ureters - had both of them re-implanted
Diabetes

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1 ARTHROTEC 75	
#2 ACETAMINOPHEN	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration from/to (or best estimate))
#1 1.000 TB BID PO	#1 JUL 9 1999 - Unknown
#2 500.000 MG PRN PO	#2 1996 - Unknown
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#1 ARTHROPATHY NOS	#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#2 GENERAL SYMPTOMS NEC	#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#1 UNK	#1 UNK
#2 UNK	#2 UNK
8. Event reappeared after reintroduction	
#1 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#2 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
VERAPAMIL	1996 - Unknown
LEVOTHYROXINE	1996 - Unknown
FLUOXETINE	1996 - Unknown
CODEINE	Unknown - Unknown
ACETAMINOPHEN	Unknown - Unknown

G. All manufacturers

1. Contact office - name/address	2. Phone number
Dennis P. Miley, M.D. G.D. Searle and Co. 9911 Woods Drive Skokie, Illinois 60077	(847) 581-7874
4. Date received by manufacturer (mortality)	5. (A) NDA #
AUG 9 1999	20-607
6. If IND, protocol #	IND #
	PLA #
7. Type of report (check all that apply)	pre-1938 <input type="checkbox"/> yes
<input type="checkbox"/> 5-day <input type="checkbox"/> 15-day	OTC product <input type="checkbox"/> yes
<input type="checkbox"/> 10-day <input checked="" type="checkbox"/> periodic	
<input checked="" type="checkbox"/> Initial <input type="checkbox"/> follow-up # 0	
	(Rev No. 0)
9. Mfr. report number	8. Adverse event term(s)
990811-SK077	HEPATIC FUNCTION ABNORMAL

E. Initial reporter

1. Name, address & phone #	2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA
MD Clinic PO Box UNITED STATES Telephone Nr:	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no	MD	<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk

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ARTHROTEC 75



3397527-0-00-02

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B. Adverse event or product problem (continued)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)
 Adverse Drug Event - statins cause muscle ache
 Race: caucasian
 Elevated GGT - March 1999

C. Suspect medication(s) (continued)

1. Name (give labeled strength & mfr/labeler, if known)	
#3 NICOBID	
#4:	
#5	
2. Dose, frequency & route used	3. Therapy dates (if unknown, give duration) <small>month (or best estimate)</small>
#3 UNKNOWN PRN PO	#3 - 3 YEARS
#4	#4
#5	#5
4. Diagnosis for use (indication)	5. Event abated after use stopped or dose reduced
#3 DISORD LIPOID METABOL	#3 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply
#4	#4 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#5	#5 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Lot # (if known)	7. Exp. date (if known)
#3 UNK	#3 UNK
#4	#4
#5	#5
8. Event reappeared after reintroduction	
#3 <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> doesn't apply	
#4 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
#5 <input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply	
9. NDC # - for product problems only (if known)	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
CARISOPRODOL	Unknown - Unknown
ENALAPRIL	1996 - Unknown
INSULIN	Unknown - Unknown
TERAZOSIN	SEP 1996 - Unknown
CONJUGATED ESTROGENS	Unknown - Unknown
MULTIVITAMINS	Unknown - Unknown
BUMETANIDE	JUL 1997 - Unknown
METOLAZONE	1996 - Unknown
AMITRIPTYLINE	APR 1999 - Unknown

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2.17HOTEC 75