



Approved by FDA on 12/2/94

WATCH

PRODUCTS REPORTING PROGRAM

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04804

FDA Use Only

A. Patient information

2. Age at time of event: 44 yrs	3. Sex <input checked="" type="checkbox"/> female <input type="checkbox"/> male	4. Weight 60.32 kgs
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B. Describe event or product problem

Event and/or Product problem (e.g., defects/malfunctions)

Attributed to adverse event (specify):

Disability: disability, congenital anomaly, required intervention to prevent permanent impairment/damage, other: _____

Duration: initial or prolonged

UNK

4. Date of this report (month/year): 01/15/99

dependence, drug withdrawal symptoms, rhea, fatigue, anxiety, feeling unwell, tingling, hot flashes, and nervousness), elevated liver function tests, and tolerance

year-old female consumer initiated in ES approximately ten years ago for back pain due to an injury. She developed tolerance to the drug and required increased doses to relieve pain. She started to take up to 20 to 30 Vicodin tablets daily. During that time period (date unknown), she developed elevated liver function tests and also noted that a physical dependence on the drug developed. She admitted herself to a drug detoxification center several times. Each time Vicodin ES was discontinued, she *

laboratory data, including dates

elevated LFT's while on Vicodin ES (exact date unknown); LFT's (date unknown) = "normal range = 5 to 52"; height= 5'

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

gynecectomy in 1988 (for pelvic inflammatory disease); no prior history of hepatic/renal dysfunction; no other known medical disorders

Factor(s): denies alcohol use

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

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)	
#1	VICODIN ES
#2	
2. Dose, frequency & route used	
#1	30 TAB daily PO
#2	
3. Therapy dates (if unknown, give duration from/to (or best estimate))	
#1	??-??-88 to ??-OCT-98
#2	
4. Diagnosis for use (indication)	
#1	back pain
#2	
5. Event abated after use stopped or dose reduced	
#1	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
6. Event reappeared after reintroduction	
#1	<input checked="" type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
#2	<input type="checkbox"/> yes <input type="checkbox"/> no <input type="checkbox"/> doesn't apply
7. Exp. date (if known)	
#1	Unknown
#2	
8. Lot # (if known)	
#1	UNKNOWN
#2	
9. NDC # - for product problems only (if known)	
#1	NI
#2	
10. Concomitant medical products and therapy dates (exclude treatment of event)	
Name: ALEVE Dates: UNK to UNK	

G. All manufacturers

1. Contact office - name/address (& mailing site for devices)		2. Phone number
Knoll Pharmaceutical Company 3000 Continental Drive - North Mount Olive, New Jersey 07828-1234		(973) 426-2600
4. Date received by manufacturer (month/year)		5. (A)NDA #
09/30/98		89-736
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 # _____		
9. Mfr. report number		8. Adverse event term(s)
USA004804		DRUG DEPENDENCE, DRUG WITHDRAWAL SYNDROME, HEPATIC FUNCTION ABNORMAL NOS, TOLERANCE
3. Report source (check all that apply)		
<input type="checkbox"/> foreign		
<input type="checkbox"/> study		
<input type="checkbox"/> literature		
<input checked="" type="checkbox"/> consumer		
<input type="checkbox"/> health professional		
<input type="checkbox"/> user facility		
<input type="checkbox"/> company representative		
<input type="checkbox"/> distributor		
<input type="checkbox"/> other:		
		UNITED STATES

E. Initial reporter

1. Name, address & phone #		2. Health professional?		3. Occupation		4. Initial reporter also sent report to FDA	
[REDACTED]		<input type="checkbox"/> yes <input checked="" type="checkbox"/> no		CONSUMER		<input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk	
[REDACTED]				USA			
[REDACTED]				Phone: [REDACTED]			

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any

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B.5. Describe event or problem

[continuation:] developed withdrawal symptoms described as diarrhea, fatigue, anxiety, feeling unwell, sweating, nervousness and hot flashes. These symptoms were treated with antidepressants, Librium, and Ativan. She checked herself out of rehabilitation and continued to use Vicodin ES. The addiction did not abate. Her physician switched her to Duract in Apr-1998 and discontinued the Vicodin ES. While on Duract, she developed horrible nightmares and her liver function tests remained elevated (LFTs = "136"). She took Duract intermittently for one month and discontinued therapy due to the nightmares. She stayed off of all medications for approximately 45 days and her LFTs improved. She restarted Vicodin ES and the addiction continued. She recently discontinued therapy in Oct-1998 and the withdrawal symptoms recurred.

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

[continuation:] Pregnant: UNK

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