



3395835-0-00-01



Approved by FDA on 12/02/93

Mfr report #	9923558
UF/Dist report #	
FDA Use Only	

MEDVIACT

THE FDA MEDICAL PRODUCTS REPORTING PROGRAM

* indicates item continued

A. Patient Information				C. Suspect medication(s)			
1. Patient Identifier [redacted] in confidence	2. Age at time of event: 50 YRS or Date of Birth:	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight UNK lbs or [redacted] kgs	1. Name (give labeled strength & mfr/labeled, if known) # 1 VIAGRA TABLETS # 2 TYLENOL			
B. Adverse event or product problem				2. Dose, frequency & route used # 1 50.00 MG TOTAL:PRN:ORAL # 2 PRN:ORAL			
1. <input checked="" type="checkbox"/> Adverse event and/or <input type="checkbox"/> Product problem (e.g. defects/malfunctions)				3. Therapy dates (if unknown, give duration) from/to (or best estimates) # 1 -/-/99 - 05/-/99 # 2 UNKNOWN			
2. Outcomes attributed to adverse event (Check all that apply) <input type="checkbox"/> death (mo/day/yr) <input type="checkbox"/> life-threatening <input type="checkbox"/> hospitalization - initial or prolonged <input type="checkbox"/> disability <input type="checkbox"/> congenital anomaly <input checked="" type="checkbox"/> required intervention to prevent permanent impairment/damage <input type="checkbox"/> other:				4. Diagnosis for use (indicate code) # 1 ERECTILE DYSFUNCTION # 2 INDICATIONS UNKNOWN			
3. Date of event 05/-/99 (mo/day/yr)				4. Date of this report 10/27/99 (mo/day/yr)		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	
5. Describe event or problem <p>THIS REPORT IS IN FOLLOW-UP TO A REPORT PREVIOUSLY SUBMITTED TO THE US FDA ON 26JUL99. THIS PHARMACIST REPORTS A MALE PATIENT STARTED ON VIAGRA (SILDENAFIL) "UP TO 100 MG" AS NEEDED FOR ERECTILE DYSFUNCTION. "SOON AFTER STARTING VIAGRA" IN MAY99, THE PATIENT'S SERUM TRANSAMINASE LEVELS "WENT FROM 50 TO 700". THE REPORTER ADDITIONALLY SUSPECTS TYLENOL (ACETAMINOPHEN) AS A POSSIBLE ETIOLOGY FOR THIS EVENT. PATIENT'S MEDICAL HISTORY IS SIGNIFICANT FOR RENAL DISEASE AND CHRONIC LIVER DISEASE.</p> <p>FOLLOW-UP (27JUL99): FOLLOW-UP INFORMATION FROM PATIENT'S PHYSICIAN INDICATES THAT THIS IS A 50 YEAR OLD PATIENT WITH CHRONIC HCV (HEPATITIS C VIRUS) - ASSOCIATED HEPATITIS. THE PATIENT HAD TRANSIENT INCREASE IN LIVER FUNCTION TESTS ABOUT THE SAME TIME HE TOOK SILDENAFIL, WHICH MAY HAVE BEEN FORTUITOUS. THE PATIENT STARTED TAKING VIAGRA 50 MG TWO TO THREE TIMES A WEEK, AS NEEDED FOR IMPOTENCE IN MAR99 OR APR99. IN APR99, PATIENT'S ALT WAS 44 U/L. IN MAY99, THE ALT LEVEL INCREASED TO 759 U/L BUT THE PATIENT WAS ASYMPTOMATIC. VIAGRA WAS PERMANENTLY DISCONTINUED IN MAY99 DUE TO THE INCREASED ALT. THE ALT LEVEL DECREASED TO 138 U/L IN JUN99, THEN FURTHER DECREASED</p>				6. Lot # (if known) # 1 UNKNOWN # 2 UNKNOWN		7. Exp. date (if known) # 1 UNKNOWN # 2 UNKNOWN	
6. Relevant tests/laboratory data, including dates MAY99: SERUM TRANSAMINASE LEVELS "WENT FROM 50 TO 700". FOLLOW-UP (27JUL99): APR99: ALT = 44 U/L MAY99: ALT = 759 U/L JUN99: ALT = 138 U/L JUL99: ALT = 80 U/L				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 type="checkbox"/> doesn't apply			
7. Other relevant history, including preexisting medical conditions (e.g. allergies, race, pregnancy, smoking & alcohol use, hepatic/renal dysfunction, etc.) CHRONIC LIVER DISEASE RENAL DISEASE: - ON DIALYSIS. CHRONIC HEPATITIS - HCV (HEPATITIS C VIRUS) ASSOCIATED. CHRONIC LUNG DISEASE				9. NDC # - for product problems only (if known) N/A			
				10. Concomitant medical products and therapy dates (exclude treatment of event) UNKNOWN			
G. All manufacturers							
1. Contact office - name/address (& mfring site for devices) PFIZER REGULATORY SAFETY PFIZER PHARMACEUTICALS 235 EAST 42 STREET NEW YORK, N.Y. 10017 U.S.A.				2. Phone number 212-573-3129			
4. Date received by manufacturer (mo/day/yr) 07/27/99				3. Report source (check all that apply) <input type="checkbox"/> foreign <input type="checkbox"/> study <input type="checkbox"/> literature <input type="checkbox"/> consumer <input checked="" type="checkbox"/> health professional <input type="checkbox"/> user facility <input type="checkbox"/> company representative <input type="checkbox"/> distributor <input type="checkbox"/> other:			
6. If IND, protocol # N/A				5. (A) NDA # NOA #29-895 IND # PLA # pre-1938 <input type="checkbox"/> yes OTC product <input type="checkbox"/> yes			
7. Type of report (check all that apply) <input type="checkbox"/> 5-day <input type="checkbox"/> 15-day <input type="checkbox"/> 10-Day <input checked="" type="checkbox"/> periodic <input type="checkbox"/> initial <input checked="" type="checkbox"/> follow-up # '1				8. Adverse event term(s) HEPATIC ENZYMES INCREASED			
9. Mfr. report number 9923558				OCT 26 1999			
E. Initial reporter							
1. Name, address & phone # [redacted] PHARM.D [redacted] STREET BOX [redacted] ATTN: [redacted] Tel. [redacted]				2. Health professional? <input checked="" type="checkbox"/> yes <input type="checkbox"/> no			
3. Occupation PHARMACIST				4. Initial reporter also sent report to FDA <input type="checkbox"/> yes <input type="checkbox"/> no <input checked="" type="checkbox"/> unk			



47 Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.



Pfizer Regulatory Safety, Pfizer Pharmaceuticals - Mfr. report # 9223538

B5. EVENT DESCRIPTION - Continued

TO 80 U/L IN JUL99. THE PATIENT WAS ALSO CONCOMITANTLY TAKING TYLENOL ON AS NEEDED BASIS. PATIENT'S MEDICAL HISTORY IS SIGNIFICANT FOR CHRONIC LIVER DISEASE AND WAS ALSO ON DIALYSIS.

E1. NAME AND ADDRESS OF PERSON - Continued

[REDACTED] MD
UNIVERSITY OF [REDACTED]
MEDICAL CENTER
[REDACTED]
Tel. [REDACTED]

OCT 26 1999