

For use by user-facilities
Importers, distributors and manufacturers
for MANDATORY reporting

MEDWATCH

Mfr Report #	1111MAXIT000X060101XNS
UF/Importer Report #	
FDA Use Only	

A. PATIENT INFORMATION			
1. Patient Identifier	2. Age at Time of event or _____ Date of birth: Year[s]	3. Sex <input type="checkbox"/> Female <input checked="" type="checkbox"/> Male	4. Weight Lbs or 63, 503 kgs
In confidence			
B. ADVERSE EVENT OR PRODUCT PROBLEM			
1. <input type="checkbox"/> Adverse Event and/or <input type="checkbox"/> Product Problem (e.g. defects/malfunctions)			
2. Outcomes Attributed to Adverse Event (check all that apply)			
<input type="checkbox"/> Death (mm/dd/yyyy)	<input type="checkbox"/> Disability or Permanent Damage	<input type="checkbox"/> Congenital Anomaly/Birth Defect	
<input type="checkbox"/> Life-threatening	<input type="checkbox"/> Other Serious (Important Medical Events)		
<input type="checkbox"/> Hospitalization - initial or prolonged	<input type="checkbox"/> Required intervention to Prevent Permanent Impairment/Damage /Devices		
3. Date of Event (mm/dd/yyyy)	4. Date of This Report (mm/dd/yyyy) 11/08/2010		
5. Describe Event or Problem			
6. Relevant Tests/Laboratory Data, Including Dates			
7. Other Relevant History, Including Preexisting Medical Conditions (e.g. allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunctions, etc.)			

C. SUSPECT PRODUCT(S)			
1. Name (Give labeled strength & mfr/labeler)			
#1 FIRMAGON			
#2			
2. Dose, Frequency & Route Used		3. Therapy Dates (if unknown, give duration from/to (or best estimate))	
#1 (80 MG 1X(continued))		#1 11/08/2010 to Unk	
#2		#2	
4. Diagnosis for Use (indication)		5. Event Abated After Use Stopped or Dose Reduced?	
#1 Prostate cancer		#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2		#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
6. Lot #	7. Exp. Date	8. Event Reappeared After Reintroduction?	
#1	#1	#1 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
#2	#2	#2 <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Doesn't Apply	
9. NDC# or Unique ID			
10. Concomitant Medical Products and Therapy Dates (Exclude treatment of event)			
BENICAR Units unknown			
TRAMADOL (Tramadol) Units unknown			
Continue...			
G. ALL MANUFACTURERS			
1. Contact Office - Name/Address (and Manufacturing Site for Devices)		2. Phone Number	
3. Report Source (Check all that apply)		4. Date Received by Manufacturer (mm/dd/yyyy)	
<input type="checkbox"/> Foreign		(A)NDA # _____	
<input type="checkbox"/> Study		IND # _____	
<input type="checkbox"/> Literature		STN # _____	
<input type="checkbox"/> Consumer		PMA/ 510(k) # _____	
<input type="checkbox"/> Health Professional		Combination Product <input type="checkbox"/> Yes	
<input type="checkbox"/> User Facility		Pre-1938 <input type="checkbox"/> Yes	
<input type="checkbox"/> Company Representative		OTC Product <input type="checkbox"/> Yes	
<input type="checkbox"/> Distributor		5. Type of Report (Check all that apply)	
<input type="checkbox"/> Other		<input type="checkbox"/> 5-day <input type="checkbox"/> 30-day	
		<input type="checkbox"/> 7-day <input type="checkbox"/> Periodic	
		<input type="checkbox"/> 10-day <input type="checkbox"/> Initial	
		<input type="checkbox"/> 15-day <input type="checkbox"/> Follow-Up #	
9. Manufacturer Report Number		8. Adverse Event Term(s)	
1111MAXIT000X060101XNS		10064353-Wrong technique	
		Continue...	
E. INITIAL REPORTER			
1. Name and Address		Phone #	
UNITED STATES			
2. Health Professional?	3. Occupation	4. Initial Reporter Also Sent Report to FDA	
<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No		<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> Unk.	

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

MEDWATCH (Continued)

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C.2 Dose, Frequency & Route Used (continued)

Suspect Product #1 (80 MG 1X SUBCUTANEOUS), Subcutaneous

C.10 Concomitant Medical Products and Therapy Dates (Exclude treatment of event) (For continuation of C.10 and/or D.11; please distinguish)

ZOCOR Units unknown

G.8 Adverse event term(s) (continued)

in drug usage process
10067482-No adverse event