

SUSPECT ADVERSE REACTION REPORT

I. REACTION INFORMATION

1. PATIENT INITIALS (first, last) K S	1a. COUNTRY UNITED STATES	2. DATE OF BIRTH			2a. AGE 24 Years	3. SEX Male	3a. WEIGHT 62.00 kg	4-6 REACTION ONSET			8-12 CHECK ALL APPROPRIATE TO ADVERSE REACTION <input type="checkbox"/> PATIENT DIED <input type="checkbox"/> INVOLVED OR PROLONGED INPATIENT HOSPITALISATION <input type="checkbox"/> INVOLVED PERSISTENT OR SIGNIFICANT DISABILITY OR INCAPACITY <input checked="" type="checkbox"/> LIFE THREATENING
		Day 15	Month OCT	Year 1994			Day 20	Month OCT	Year 2018		
7 + 13 DESCRIBE REACTION(S) (including relevant tests/lab data) Event Verbatim [PREFERRED TERM] (Related symptoms if any separated by commas) Fever [Pyrexia]											

II. SUSPECT DRUG(S) INFORMATION

14. SUSPECT DRUG(S) (include generic name) #1) Rx Prod 2 (RX Prod 1 Gen) Tablet, 100 mg {Lot # R-123}		20. DID REACTION ABATE AFTER STOPPING DRUG? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
15. DAILY DOSE(S) #1) 50 mg, bid	16. ROUTE(S) OF ADMINISTRATION #1) Oral	
17. INDICATION(S) FOR USE #1) Pyrexia (Pyrexia)		21. DID REACTION REAPPEAR AFTER REINTRODUCTION? <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> NA
18. THERAPY DATES(from/to) #1) 20-JUL-2018 / 28-SEP-2018	19. THERAPY DURATION #1) 70 days	

III. CONCOMITANT DRUG(S) AND HISTORY

22. CONCOMITANT DRUG(S) AND DATES OF ADMINISTRATION (exclude those used to treat reaction)		
23. OTHER RELEVANT HISTORY. (e.g. diagnostics, allergies, pregnancy with last month of period, etc.) From/To Dates Type of History / Notes Description Unknown		

IV. MANUFACTURER INFORMATION

24a. NAME AND ADDRESS OF MANUFACTURER ARGUS SAFETY UNITED STATES		26. REMARKS Medically Confirmed: Yes
	24b. MFR CONTROL NO. 19US000521	25b. NAME AND ADDRESS OF REPORTER Mr Jason Mark Brown UNITED STATES
24c. DATE RECEIVED BY MANUFACTURER 06-JAN-2019	24d. REPORT SOURCE <input type="checkbox"/> STUDY <input type="checkbox"/> LITERATURE <input checked="" type="checkbox"/> HEALTH PROFESSIONAL <input checked="" type="checkbox"/> OTHER: Spontaneous	
DATE OF THIS REPORT 09-JAN-2019	25a. REPORT TYPE <input checked="" type="checkbox"/> INITIAL <input type="checkbox"/> FOLLOWUP:	