

Adverse Event Form

A. Patient information	13. Relevant tests/laboratory data, including dates
Patient Initials 2. Age at time of event 3. Gender	
or M F	
Date of Birth	
4. Weight:/ 5. Country:	14. Other relevant history, including pre-existing medical conditions (e.g., allergies,
kg. dd / mm / yyyy	race, pregnancy, smoking alcohol use, hepatic/renal dysfunction, etc.)
8.44	
B. Adverse Event Content	15. Seriousness of the event: Is the event Serious or Non-serious
c. Bate witch event started (comminy))),	If Serious, then Choose the criteria
7 Date of the control	Death (dd/mm/yyyy)// Results in persistent or significant
7. Date of recovery (dd/mm/yyyy)://	disability/incapacity
8. Describe event:	Life threatening Congenital anomaly/Birth defect
	Congenital anomaly/birth delect
	Requires inpatient hospitalization or Other medically important condition
	prolongation of hospitalization
	16. Outcomes
Relationship of event to the suspected medication	Fatal Continuing Recovering Recovered
Related Not related	Other (specify)
C. Suspected medication(s)	
Batch No. /	Reason for use or
10 Name	
10. Name Manufacturer Lot No. (if Sr.No. generic name) (if known) known)	Exp. Date Dose Route Date pres-cribed (if known) used used Frequency started stopped for
/brand and / or Manufacturer Lot No. (II	Expression and a substitution an
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