INBIOTECH FORM FOR ADR REPORT
V 1.0

ADMINISTRATIVE		
Initial/Follow Up		
Report Type:		
Medically confirmed:	☐ Yes	☐ No
Received date: dd/mm/yyyy		
Internal No (for controlling):	No	
Reg. No to the controlling body:		
REPORTER		
Name:		
Address:		
City:		
State:		
Telephone:		
Reporter type:		
If not a HCP, please specify		
Report date:		
PATIENT DATA		
Initials:		
Sex:		
Occupation:		
Date of birth: dd/mm/yyyy		
If not available, age	Years	
If not available, age group		
Height	cm	
Weight	kg	
MEDICAL HISTORY/ RISK FACTORS		
Any present and/or past related medical history (incl. concomitant diseases, allergy, smoking, abuse with harmful substances, previous exposure to the same or similar medicinal product):	☐ Yes If Yes, please specify	☐ No
ADVERSE REACTION (AR)		
Reported AR		
Date of oncet of AR:		

dd/mm/yyyy Date of stop of AR: dd/mm/yyyy		
Ongoing at the time of the reporting:	☐ Yes	☐ No
Duration (if < 24 hrs):	Hours	Minutes
AR resulted in:		
Date of death: dd/mm/yyyy		
Autopsy performed:	☐ Yes Date	☐ No
If the answer is Yes, please write down the results from the autopsy or summarize the autopsy report to the related laboratory values, or ask for it the reporter		
Possible reason for the death:		
Descrption: (Description of the event)		
Seriousness	☐ Serious	☐ Not serious
If serious:	**Seriousness criteria:**	
	☐ Death	☐ Persistent or significant disability/ incapacity
	☐ Life-threatening	☐ Congenital anomaly/Birth defect.
	☐ Inpatient hospitalisation or prolongation of existing hospitalisation	☐ Medically important
RELATED LABORATORY TESTS:	*If yes, please specify below or add info*	
	Date: Test and result: Reference values:	
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values:

MEDICINAL TREATMENT	**Form**	**Administration**	**Dose (unit)**	**Daily dose**	**Start** dd/mm/yyyy	**End** dd/mm/yyyy	**Indication**
Suspected medicinal product(s)							
	Tab		mg	mg			
	Tab		mg	mg			
	Tab		mg	mg			
	Tab		mg	mg			
	Tab		mg	mg			
Concomitant medicinal product(s)							
	Tab		mg	mg			
	Tab		mg	mg			
	Tab		mg	mg			
	Tab		mg	mg			
	Tab		mg	mg			
	Tab		mg	mg			
	Tab		mg	mg			
	Tab		mg	mg			
	Tab		mg	mg			
	Tab		mg	mg			

ACTIONS TAKEN in response to the ***adverse drug reaction***	
Medicinal treatment:	
☐ Continued, no change	Specify the product(s):
☐ Changed	Specify the product(s):
☐ Discontinued	Specify the product(s):
Describe the rescue measures and investigations taken in response to the event	
Has the event resolved after the discontinuation of the medication?	
Has the event recurred after the administration is reintroduced?	
NOTIFICATION	
Has the event been reported to a regulatory body?	☐ Yes Date ☐ No