

General Information	
EudraVigilance Local Report Number	EU-EC-10011073362
Sender Type	Health professional
Sender's Organisation	MODERNA BIOTECH SPAIN S.L.
Type of Report	Spontaneous
Primary source country	Non-European Economic Area
Reporter's qualification	Healthcare Professional
Case serious?	Yes

Patient		
Age Group	Age Group (as per reporter)	Sex
12-17 Years		Female

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness ¹
Cardiac arrest	2.0 Days	Fatal	death., other
Dizziness		Recovered/Resolved	
Headache		Unknown	
Pyrexia		Unknown	
Nausea		Unknown	
Brain herniation	2.0 Days	Fatal	death., other
Brain injury	2.0 Days	Fatal	death., hospital., other
Multiple organ dysfunction syndrome	2.0 Days	Fatal	death., other

Drug Information					
Role ²	Drug	Duration	Dose	Units in Interval	Action taken
S	SPIKEVAX - ELASOMERAN		1.0 {DF}		Unknown

Drug Information (cont.)				
Info ³	Drug	Indication	Pharm. Form	Route of Admin.
	SPIKEVAX - ELASOMERAN	COVID-19 vaccination		Intramuscular use

Rechallenge matrix table		
Reaction/Event (MedDRA LLT)	Drug	Rechallenge? / Reaction recurred?
Brain herniation	SPIKEVAX - ELASOMERAN	no - n/a
Brain injury	SPIKEVAX - ELASOMERAN	no - n/a
Cardiac arrest	SPIKEVAX - ELASOMERAN	no - n/a
Dizziness	SPIKEVAX - ELASOMERAN	no - n/a
Headache	SPIKEVAX - ELASOMERAN	no - n/a
Multiple organ dysfunction syndrome	SPIKEVAX - ELASOMERAN	no - n/a
Nausea	SPIKEVAX - ELASOMERAN	no - n/a
Pyrexia	SPIKEVAX - ELASOMERAN	no - n/a

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Seriousness: **death**=results in death; **life threat**=life threatening; **hospital**=requires hospitalization/prolongation of hospitalization; **disability**=results in disability/incapacity; **congen**=congenital anomaly/birth defect; **other**=other medically important information; **(blank)**=non-serious

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Drug role: **S**=suspect; **C**=concomitant; **I**=interacting; **N**=not administered

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Additional Information on Drug: **1**=Counterfeit; **2**= Overdose; **3**=Drug taken by the father; **4**=Drug taken beyond expiry date; **5**=Batch and lot tested and found within specifications; **6**=Batch and lot tested and found not within specifications; **7**=Medication error; **8**=Misuse; **9**=Abuse; **10**=Occupational exposure; **11**=Off label use; **(blank)** =no additional information

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