

General Information	
EudraVigilance Local Report Number	EU-EC-10010889205
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		Male

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness ¹
Fever		Fatal	death.
Seizure		Fatal	death., other
Headache		Fatal	death.

Drug Information					
Role ²	Drug	Duration	Dose	Units in Interval	Action taken
S	SPIKEVAX - ELASOMERAN		1.0 {DF}		Not applicable

Drug Information (cont.)				
Info ³	Drug	Indication	Pharm. Form	Route of Admin.
	SPIKEVAX - ELASOMERAN	Product used for unknown indication		Intramuscular use

Rechallenge matrix table		
Reaction/Event (MedDRA LLT)	Drug	Rechallenge? / Reaction recurred?
Fever	SPIKEVAX - ELASOMERAN	no - n/a
Headache	SPIKEVAX - ELASOMERAN	no - n/a
Seizure	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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