

General Information

EudraVigilance Local Report Number

EU-EC-10008125245

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

3-11 Years

Age Group (as per reporter)

Sex

Male

Reaction / Event

MedDRA LLT	Duration	Outcome	Seriousness ¹
Nausea		Unknown	
Chills	1.0 Days	Unknown	
Cardiac arrest		Fatal	death.
Musculoskeletal stiffness		Unknown	
Headache		Unknown	
Feeling abnormal		Unknown	
Pyrexia	2.0 Days	Unknown	
Vomiting	2.0 Days	Unknown	

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	COVID-19 vaccination		Intramuscular use

Rechallenge matrix table

Reaction/Event (MedDRA LLT)	Drug	Rechallenge? / Reaction recurred?
Cardiac arrest	SPIKEVAX - ELASOMERAN	no - n/a
Chills	SPIKEVAX - ELASOMERAN	no - n/a
Feeling abnormal	SPIKEVAX - ELASOMERAN	no - n/a
Headache	SPIKEVAX - ELASOMERAN	no - n/a
Musculoskeletal stiffness	SPIKEVAX - ELASOMERAN	no - n/a
Nausea	SPIKEVAX - ELASOMERAN	no - n/a
Pyrexia	SPIKEVAX - ELASOMERAN	no - n/a
Vomiting	SPIKEVAX - ELASOMERAN	no - n/a

1

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

2

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

3

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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Page 1 of 1