

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	Age Group	Sex
6 Years		Male

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

Drug Information					
Role ²	Drug	Duration	Dose	Units in Interval	Action taken
S	COVID-19 MRNA VACCINE MODERNA (CX-024414) - COVID-19 MRNA VACCINE MODERNA (CX-024414)		1.0 (DF)		Not applicable

Drug Information (cont.)				
Info ³	Drug	Indication	Pharm. Form	Route of Admin.
	COVID-19 MRNA VACCINE MODERNA (CX-024414) - COVID-19 MRNA VACCINE MODERNA (CX-024414)	COVID-19 vaccination		Intramuscular

Rechallenge matrix table		
Reaction/Event (MedDRA LLT)	Drug	Rechallenge? / Reaction recurred?
Cardiac arrest	COVID-19 MRNA VACCINE MODERNA (CX-024414) - COVID-19 MRNA VACCINE MODERNA (CX-024414)	no - n/a
Chills	COVID-19 MRNA VACCINE MODERNA (CX-024414) - COVID-19 MRNA VACCINE MODERNA (CX-024414)	no - n/a
Feeling abnormal	COVID-19 MRNA VACCINE MODERNA (CX-024414) - COVID-19 MRNA VACCINE MODERNA (CX-024414)	no - n/a
Headache	COVID-19 MRNA VACCINE MODERNA (CX-024414) - COVID-19 MRNA VACCINE MODERNA (CX-024414)	no - n/a
Musculoskeletal stiffness	COVID-19 MRNA VACCINE MODERNA (CX-024414) - COVID-19 MRNA VACCINE MODERNA (CX-024414)	no - n/a
Nausea	COVID-19 MRNA VACCINE MODERNA (CX-024414) - COVID-19 MRNA VACCINE MODERNA (CX-024414)	no - n/a
Pyrexia	COVID-19 MRNA VACCINE MODERNA (CX-024414) - COVID-19 MRNA VACCINE MODERNA (CX-024414)	no - n/a
Vomiting	COVID-19 MRNA VACCINE MODERNA (CX-024414) - COVID-19 MRNA VACCINE MODERNA (CX-024414)	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