

General Information

EudraVigilance Local Report Number

EU-EC-10010193681

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

12-17 Years

Age Group (as per reporter)

Sex

Male

Reaction / Event

MedDRA LLT

Cerebral haemorrhage

Cerebral ventricular rupture

Duration

4.0 Days

4.0 Days

Outcome

Fatal

Fatal

Seriousness¹

death., hospital., other

death., hospital., other

Drug Information

Role²

S

Drug

SPIKEVAX - ELASOMERAN

Duration

1.0 Days

Dose

1.0 {DF}

Units in Interval

Action taken

Not applicable

Drug Information (cont.)

Info³

Drug

SPIKEVAX - ELASOMERAN

Indication

COVID-19 vaccination

Pharm. Form

Route of Admin.

Intramuscular use

Rechallenge matrix table

Reaction/Event (MedDRA LLT)

Cerebral haemorrhage

Cerebral ventricular rupture

Drug

SPIKEVAX - ELASOMERAN

SPIKEVAX - ELASOMERAN

Rechallenge? / Reaction recurred?

no - n/a

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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