

General Information	
EudraVigilance Local Report Number	EU-EC-10010656124
Sender Type	Regulatory authority
Sender's Organisation	EEA Regulator
Type of Report	Spontaneous
Primary source country	European Economic Area
Reporter's qualification	Non-Healthcare Professional
Case serious?	Yes

Patient		
Age Group	Age Group (as per reporter)	Sex
More than 85 Years		Female

Reaction / Event			
MedDRA LLT	Duration	Outcome	Seriousness ¹
Breast cancer female	99.0 Days	Recovered/Resolved With Sequelae	life threat., other

Drug Information					
Role ²	Drug	Duration	Dose	Units in Interval	Action taken
S	SPIKEVAX - ELASOMERAN		1.0 {DF}		
S	- ESCITALOPRAM				
C	- ACETYLSALICYLIC ACID				
C	- LEVOTHYROXINE SODIUM				
C	- METOPROLOL TARTRATE, METOPROLOL TARTRATE BP				
C	- PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE				

Drug Information (cont.)				
Info ³	Drug	Indication	Pharm. Form	Route of Admin.
	SPIKEVAX - ELASOMERAN	COVID-19 immunisation		
	- ESCITALOPRAM	N/A		Oral use
	- ACETYLSALICYLIC ACID	N/A		Oral use
	- LEVOTHYROXINE SODIUM	N/A		Oral use
	- METOPROLOL TARTRATE, METOPROLOL TARTRATE BP	N/A		Oral use
	- PANTOPRAZOLE, PANTOPRAZOLE SODIUM, PANTOPRAZOLE SODIUM SESQUIHYDRATE	N/A		Oral use

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