Report	ort COVID-19 VACCINE JANSSEN (AD26.COV2.S)												
EU Local Number	EV Gatew ay Receip t Date	Report Type	Primary Source Qualific ation	Primar y Sourc e Count ry for Regula tory Purpo ses	Litera ture Refer ence	Patie nt Age Grou p	Patie nt Age Grou p (as per repor ter)	Patie nt Sex	Par ent Chil d Rep ort	Reaction List PT (Duration – Outcome - Seriousness Criteria)	Suspect/interacti ng Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	Concomitan t/Not Administere d Drug List (Drug Char - Indication PT - Action taken - [Duration - Dose - Route])	ICS R For m
EU-EC- 100082 22359	07/04/ 2021	Sponta neous	Non Healthc are Professi onal	Non Europ ean Econo mic Area	Not availa ble	18- 64 Years	Adult	Not Speci fied	No	Death (n/a - Fatal - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICS R
EU-EC- 100081 95117	05/04/ 2021	Sponta neous	Healthc are Professi onal	Non Europ ean Econo mic Area	Not availa ble	More than 85 Years	Elderl y	Fema le	No	Cardiac arrest (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICS R
EU-EC- 100081 97653	05/04/ 2021	Sponta neous	Non Healthc are Professi onal	Non Europ ean Econo mic Area	Not availa ble	More than 85 Years	Elderl y	Fema le	No	Atrial fibrillation (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition),	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable -	Not reported	ICS R

										Dysphagia (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Hypotension (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition), Peripheral embolism (n/a - Unknown - Results in Death, Caused/Prolonged Hospitalisation, Other Medically Important Condition)	[n/a - n/a - Unknown])		
EU-EC- 100081 64806	01/04/ 2021	Sponta neous	Non Healthc are Professi onal	Non Europ ean Econo mic Area	Not availa ble	Not Speci fied	Not Speci fied	Male	No	COVID-19 (n/a - Unknown - Results in Death, Other Medically Important Condition), Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICS R
EU-EC- 100081 52972	31/03/ 2021	Sponta neous	Non Healthc are Professi onal	Non Europ ean Econo mic Area	Not availa ble	Not Speci fied	Not Speci fied	Fema le	No	Death (n/a - Fatal - Results in Death, Other Medically Important Condition)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a - Unknown])	Not reported	ICS R
EU-EC- 100081 35660	30/03/ 2021	Sponta neous	Non Healthc are Professi onal	Non Europ ean Econo mic Area	Not availa ble	Not Speci fied	Not Speci fied	Fema le	No	Death (n/a - Fatal - Results in Death), Pain in extremity (n/a - Unknown - Results in Death)	COVID-19 VACCINE JANSSEN (AD26.COV2.S) [COVID-19 VACCINE JANSSEN (AD26.COV2.S)] (S - Immunisation - Not applicable - [n/a - n/a -	Not reported	ICS R

											Unknown])		
EU-EC-	30/03/	Sponta	Healthc	Non	Not	18-	Adult	Fema	No	Abdominal pain upper (n/a - Unknown - Results	COVID-19	Not	<u>ICS</u>
100081 38926	2021	neous	are Professi	Europ ean	availa ble	64 Years		le		in Death),	VACCINE JANSSEN (AD26.COV2.S)	reported	<u>R</u>
33723			onal	Econo	2.0					Death (n/a - Fatal - Results in Death),	[COVID-19		
				mic Area							VACCINE JANSSEN (AD26.COV2.S)] (S		
				Alea						Ear pain (n/a - Unknown - Results in Death),	- Immunisation -		
										Fatigue (n/a - Unknown - Results in Death),	Not applicable -		
										ratigue (ii/a - Ofikilowii - Results iii Deatil),	[n/a - n/a - Unknown])		
										Headache (n/a - Unknown - Results in Death),	1,		
										Pain in extremity (n/a - Unknown - Results in Death),			
										Pallor (n/a - Unknown - Results in Death),			
										Pre-existing condition improved (n/a - Unknown			
										- Results in Death)			