FOI 2025/00385 - Vaxelis 6-in-1 Vaccine Analysis Print.
All UK spontaneous suspected Adverse Drug Reaction (ADR) reports associated with the
Vaxelis 6-in-1 vaccine up to and including 14/05/2025.
Report run: 15/05/2025
Earliest reaction date: 21/03/2022

Reaction MedDRA SOC Name	Reaction MedDRA HLGT Name	Reaction MedDRA HLT Name	Reaction MedDRA PT Name	Reaction Total	Fatal
Gastrointestinal disorders	Gastrointestinal signs and symptoms	Nausea and vomiting symptoms	Nausea	1	0
			Vomiting	2	0
	Oral soft tissue conditions	Oral soft tissue signs and symptoms	Oral pain	1	0
		Stomatitis and ulceration	Stomatitis	1	0
	Total			**5**	**0**
General disorders and administration site conditions	Administration site reactions	Vaccination site reactions	Extensive swelling of vaccinated limb	1	0
	Body temperature conditions	Febrile disorders	Pyrexia	3	0
	Fatal outcomes	Death and sudden death	Death	1	0
	General system disorders NEC	General signs and symptoms NEC	Crying	1	0
			High-pitched crying	1	0
			Peripheral swelling	1	0
			Swelling	1	0
		Pain and discomfort NEC	Pain	1	0
	Total			**10**	**0**
Injury, poisoning and procedural complications	Medication errors and other product use errors and issues	Medication errors, product use errors and issues NEC	Product use in unapproved indication	1	0
		Product administration errors and issues	Incorrect route of product administration	1	0
	Total			**2**	**0**
Nervous system disorders	Seizures (incl subtypes)	Seizures and seizure disorders NEC	Seizure	3	0
	Total			**3**	**0**
Respiratory, thoracic and mediastinal disorders	Respiratory disorders NEC	Breathing abnormalities	Dyspnoea	1	0
	Total			**1**	**0**
Skin and subcutaneous tissue disorders	Angioedema and urticaria	Urticarias	Urticaria	2	0
	Epidermal and dermal conditions	Dermal and epidermal conditions NEC	Skin reaction	1	0
		Erythemas	Erythema	1	0

		Rashes, eruptions and exanthems NEC	Rash	1	0
	Skin vascular abnormalities	Skin vasomotor conditions	Livedo reticularis	1	0
	Total			**6**	**0**
Vascular disorders	Vascular disorders NEC	Site specific vascular disorders NEC	Pallor	1	0
	Total			**1**	**0**
TOTAL REACTIONS FOR DRUG				**28**	
TOTAL REPORTS				**16**	
TOTAL FATAL OUTCOME REPORTS					**0**