

Table 1 - Total number of UK spontaneous suspected adverse drug reaction (ADR) Yellow Card reports associated with Levobupivacaine with data lock point of up to including 11/06/2026

Case number	Year	Suspect drug	Suspect Drug Dose	Suspect Drug Dose Unit	Route Of Administration	Suspect Drug Indication	Suspect Drug Duration (days)	Reaction Time to Onset (days)	Reaction MedDRA PT Name	Outcome Of Reaction Event
1	2005	LEVOBUPIVACAINE			EPIDURAL USE	Anaesthesia			Blindness transient	recovered/resolved
									Generalised tonic-clonic seizure	recovered/resolved
									Headache	recovered/resolved
									Pyrexia	recovered/resolved
2	2005	LEVOBUPIVACAINE			EPIDURAL USE				Blood pressure increased	recovered/resolved
									Heart rate increased	recovered/resolved
									Loss of consciousness	recovered/resolved
									Neuromuscular blockade	recovered/resolved
3	2003	LEVOBUPIVACAINE			EPIDURAL USE	Analgesic therapy			Respiratory failure	unknown
									Hypotension	recovered/resolved
4	2003	LEVOBUPIVACAINE			EPIDURAL USE	Analgesic therapy			Neuromuscular block prolonged	recovered/resolved
									Hypotension	recovered/resolved
5	2003	LEVOBUPIVACAINE			EPIDURAL USE	Analgesic therapy			Neuromuscular block prolonged	recovered/resolved
									Hypotension	recovered/resolved
6	2003	LEVOBUPIVACAINE			EPIDURAL USE	Analgesic therapy			Neuromuscular block prolonged	recovered/resolved
									Hypotension	unknown
7	2004	LEVOBUPIVACAINE			EPIDURAL USE				Neuromuscular block prolonged	recovered/resolved
									Hypoaesthesia	recovering/resolving
									Lumbar radiculopathy	recovering/resolving
									Blood pressure decreased	recovering/resolving
8	2002	LEVOBUPIVACAINE			EPIDURAL USE				Dyspnoea	unknown
									Oxygen saturation decreased	recovering/resolving
									Praesthesia	recovered/resolved
									Speech disorder	unknown
									Spinal anaesthesia	recovered/resolved
									Muscular weakness	recovered/resolved
									Asthenia	recovering/resolving
9	2009	LEVOBUPIVACAINE	3	mg	EPIDURAL USE	Pain in extremity			Hypoaesthesia	recovering/resolving
									Paralysis	recovering/resolving
									Anal incontinence	not recovered/not resolved/ongoing
									Areflexia	not recovered/not resolved/ongoing
10	2010	LEVOBUPIVACAINE	10	ml	EPIDURAL USE	Procedural pain			Paraesthesia	not recovered/not resolved/ongoing
									Paralysis	not recovered/not resolved/ongoing
									Pyrexia	not recovered/not resolved/ongoing
									Dysarthria	recovering/resolving
11	2010	LEVOBUPIVACAINE			EPIDURAL USE	Pain	1		Facial paralysis	recovering/resolving
									Hemiparesis	recovering/resolving
									Muscular weakness	recovering/resolving
									Transient ischaemic attack	recovering/resolving
12	2009	LEVOBUPIVACAINE			EPIDURAL USE	Pain	1		Abdominal pain upper	not recovered/not resolved/ongoing
									Anxiety	not recovered/not resolved/ongoing
									Burning sensation	not recovered/not resolved/ongoing
									Cauda equina syndrome	not recovered/not resolved/ongoing
13	2012	LEVOBUPIVACAINE			EPIDURAL USE	Spinal column injury	1	3	Dizziness	not recovered/not resolved/ongoing
									Feeling abnormal	not recovered/not resolved/ongoing
									Hypersensitivity	not recovered/not resolved/ongoing
									Hypertension	not recovered/not resolved/ongoing
									Hypoaesthesia	not recovered/not resolved/ongoing
									Muscle spasms	not recovered/not resolved/ongoing
									Paraesthesia	not recovered/not resolved/ongoing
									Pruritus allergic	not recovered/not resolved/ongoing
									Unevaluable event	unknown
									Vision blurred	not recovered/not resolved/ongoing
									Abdominal pain upper	not recovered/not resolved/ongoing
									Anxiety	not recovered/not resolved/ongoing
									Burning sensation	not recovered/not resolved/ongoing
									Cauda equina syndrome	not recovered/not resolved/ongoing
									Dizziness	not recovered/not resolved/ongoing
									Feeling abnormal	not recovered/not resolved/ongoing
									Hypersensitivity	not recovered/not resolved/ongoing
									Hypertension	not recovered/not resolved/ongoing
									Hypoaesthesia	not recovered/not resolved/ongoing
									Muscle spasms	not recovered/not resolved/ongoing
									Paraesthesia	not recovered/not resolved/ongoing
									Pruritus allergic	not recovered/not resolved/ongoing
									Unevaluable event	unknown
									Vision blurred	not recovered/not resolved/ongoing
14									Abdominal pain upper	not recovered/not resolved/ongoing
									Anxiety	not recovered/not resolved/ongoing
									Burning sensation	not recovered/not resolved/ongoing
									Cauda equina syndrome	not recovered/not resolved/ongoing

								71	Dizziness	not recovered/not resolved/ongoing
									Feeling abnormal	not recovered/not resolved/ongoing
									Hypersensitivity	not recovered/not resolved/ongoing
									Hypertension	not recovered/not resolved/ongoing
									Hypoaesthesia	not recovered/not resolved/ongoing
									Muscle spasms	not recovered/not resolved/ongoing
									Paraesthesia	not recovered/not resolved/ongoing
									Pruritus allergic	not recovered/not resolved/ongoing
									Unevaluable event	unknown
									Vision blurred	not recovered/not resolved/ongoing
14	2013	LEVOBUPIVACAINE	0	%	EPIDURAL USE				Abnormal behaviour	recovered/resolved
									Exposure during pregnancy	unknown
									Hypersensitivity	unknown
									Incorrect route of product administration	unknown
									Pruritus	unknown
									Psychotic disorder	recovered/resolved
15	2014	LEVOBUPIVACAINE			EPIDURAL USE				Anaesthetic complication cardiac	recovered/resolved
									Cardiac arrest	recovered/resolved
									Maternal exposure during pregnancy	unknown
									Procedural headache	recovered/resolved
									Documented hypersensitivity to administered product	unknown
16	2015	LEVOBUPIVACAINE	7	ml	EPIDURAL USE				Dyspnoea	recovered/resolved
									Erythema	recovered/resolved
									Nausea	recovered/resolved
									Pain	recovered/resolved
									Pruritus	recovered/resolved
									Swelling	recovered/resolved
									Confusion postoperative	unknown
17	2015	LEVOBUPIVACAINE			EPIDURAL USE	Epidural anaesthesia		1	Mental status changes postoperative	recovering/resolving
									Metabolic alkalosis	unknown
									Unevaluable event	unknown
18	2018	LEVOBUPIVACAINE			EPIDURAL USE	Epidural analgesia		1	Therapeutic product effect prolonged	recovered/resolved
19	2018	LEVOBUPIVACAINE			EPIDURAL USE				Therapeutic product effect prolonged	recovered/resolved
20	2017	LEVOBUPIVACAINE			EPIDURAL USE	Epidural anaesthesia			Cardiac arrest	unknown
									Arrhythmia	recovered/resolved
									Cardiac arrest	recovered/resolved
21	2017	LEVOBUPIVACAINE	20	ml	EPIDURAL USE	Epidural anaesthesia			Hypoaesthesia oral	recovered/resolved
									Limb discomfort	recovered/resolved
									Respiratory arrest	recovered/resolved
22	2016	LEVOBUPIVACAINE	10	ml	EPIDURAL USE	Epidural anaesthesia			Generalised tonic-clonic seizure	recovered/resolved
23	2021	LEVOBUPIVACAINE			EPIDURAL USE	Epidural anaesthesia			Exposure during pregnancy	recovered/resolved
									No adverse event	recovered/resolved
									Generalised tonic-clonic seizure	recovered/resolved
									Muscle twitching	recovered/resolved
24	2021	LEVOBUPIVACAINE	0	%	EPIDURAL USE	Analgesic therapy			Off label use	unknown
									Post lumbar puncture syndrome	recovered/resolved
									Product use issue	unknown
									Subdural haematoma	recovered/resolved
									Subdural haemorrhage	recovered/resolved
									Subdural hygroma	recovered/resolved
									Anaesthetic complication	recovered/resolved
									Arrested labour	recovered/resolved
									Exposure during pregnancy	recovered/resolved
									Foetal heart rate deceleration abnormality	recovered/resolved
25	2021	LEVOBUPIVACAINE	10	ml	EPIDURAL USE				Anaesthetic complication	recovered/resolved
					EPIDURAL USE	Epidural analgesia			Arrested labour	recovered/resolved
									Exposure during pregnancy	recovered/resolved
									Foetal heart rate deceleration abnormality	recovered/resolved
26	2023	LEVOBUPIVACAINE			EPIDURAL USE	Labour induction			Exposure during pregnancy	unknown
									Live birth	unknown
27	2023	LEVOBUPIVACAINE			EPIDURAL USE	Anaesthesia			Exposure during pregnancy	unknown
									Live birth	unknown
									Arachnoiditis	unknown
									Cauda equina syndrome	unknown
									Constipation	unknown
									Maternal exposure during delivery	unknown

28	2023	LEVOBUPIVACAINE	3	ml	EPIDURAL USE		1		Maternal exposure during pregnancy	unknown					
								Motor dysfunction	recovering/resolving						
								Muscular weakness	recovering/resolving						
								Nerve injury	unknown						
								Paralysis	not recovered/not resolved/ongoing						
								Pyrexia	unknown						
								Sensory loss	recovering/resolving						
								Arachnoiditis	unknown						
								Cauda equina syndrome	unknown						
								Constipation	unknown						
								Maternal exposure during delivery	unknown						
								Maternal exposure during pregnancy	unknown						
								Motor dysfunction	recovering/resolving						
								Muscular weakness	recovering/resolving						
29	2024	LEVOBUPIVACAINE	98	ml	EPIDURAL USE		1		Nerve injury	unknown					
									Paralysis	not recovered/not resolved/ongoing					
									Pyrexia	unknown					
									Sensory loss	recovering/resolving					
									Movement disorder	recovering/resolved					
									Product use issue	recovering/resolved					
									Movement disorder	recovering/resolved					
									Product use issue	recovering/resolved					
									Drug ineffective	unknown					
									Dyskinesia	recovering/resolved					
									Maternal exposure during pregnancy	recovering/resolved					
									Normal newborn	recovering/resolved					
									Drug ineffective	unknown					
									Dyskinesia	recovering/resolved					
30	2024	LEVOBUPIVACAINE	4	mL	Epidural use	Epidural analgesia			Maternal exposure during pregnancy	recovering/resolved					
								Normal newborn	recovering/resolved						
								Drug ineffective	unknown						
								Dyskinesia	recovering/resolved						
								Maternal exposure during pregnancy	recovering/resolved						
								Normal newborn	recovering/resolved						
								Drug ineffective	unknown						
								Dyskinesia	recovering/resolved						
								Maternal exposure during pregnancy	recovering/resolved						
								Normal newborn	recovering/resolved						
								Horner's syndrome	recovering/resolved						
								Live birth	unknown						
								Maternal exposure during pregnancy	unknown						
								Horner's syndrome	recovering/resolved						
					Maternal exposure during delivery	recovering/resolved									
31	2025	LEVOBUPIVACAINE	10	mL	Epidural use	Epidural analgesia			Normal newborn	recovering/resolved					
														Horner's syndrome	recovering/resolved
														Maternal exposure during delivery	recovering/resolved
														Normal newborn	recovering/resolved
														Horner's syndrome	recovering/resolved
														Maternal exposure during delivery	recovering/resolved
														Normal newborn	recovering/resolved
														Horner's syndrome	recovering/resolved
														Maternal exposure during pregnancy	recovering/resolved
														Normal newborn	recovering/resolved
														Horner's syndrome	recovering/resolved
														Maternal exposure during pregnancy	unknown
														Normal newborn	unknown
														Horner's syndrome	recovering/resolved
					Maternal exposure during delivery	recovering/resolved									
32	2025	LEVOBUPIVACAINE	20	mL	Epidural use	Epidural analgesia			Normal newborn	recovering/resolved					
														Horner's syndrome	recovering/resolved
														Maternal exposure during pregnancy	recovering/resolved
														Normal newborn	recovering/resolved
														Horner's syndrome	recovering/resolved
														Maternal exposure during pregnancy	unknown
														Normal newborn	unknown
														Horner's syndrome	recovering/resolved
														Maternal exposure during delivery	recovering/resolved
														Normal newborn	recovering/resolved
														Horner's syndrome	recovering/resolved
														Maternal exposure during pregnancy	unknown
														Normal newborn	unknown
														Horner's syndrome	recovering/resolved
					Maternal exposure during delivery	recovering/resolved									
33	2025	LEVOBUPIVACAINE			Epidural use	Epidural analgesia			Normal newborn	recovering/resolved					
														Horner's syndrome	recovering/resolved
														Maternal exposure during pregnancy	unknown
														Normal newborn	unknown
														Horner's syndrome	recovering/resolved
														Maternal exposure during delivery	recovering/resolved
														Normal newborn	recovering/resolved
														Horner's syndrome	recovering/resolved
														Maternal exposure during pregnancy	unknown
														Normal newborn	unknown
														Horner's syndrome	recovering/resolved
														Maternal exposure during delivery	recovering/resolved
														Normal newborn	recovering/resolved
														Horner's syndrome	recovering/resolved