VETERINARY PHARMACOVIGILANCE

REPORT FOR SUSPECTED ADVERSE REACTIONS IN ANIMALS OR IN HUMANS AFTER THE USE OF A VETERINARY MEDICINE

	SENDER REPORT IDENTIFICATION-CASE REF.No: Page 1 of 3 2025-UK-008510								
Safety issues in animals in humans	Reporting country: United Kingdom								
Lack of expected efficacy	Purchase country: United Kingdom								
Withdrawal period issues	Report source: Owner								
1. ADDRESS OF COMPETENT AUTHORITY	· · · · · · · · · · · · · · · · · · ·								
1. ADDRESS OF COMPETENT AUTHORITY	2. NAME AND ADDRESS OF SENDER								
Date complaint received by sender: 2-Jun-2025 (dd-Mon-yyyy)	5								
Type of report Initial Follow-up	(date, case number)								
Person who reported the reaction : veterinarian owner	physician pharmacist other:								
3. VETERINARIAN/PHYSICIAN/PHARMACIST 4. ANIMAL OWNER / HUMAN PATIENT									
5. ANIMAL DATA No. of animals treated: 1 Animal characteristics (animal(s) showing signs):	No. of animals showing signs: 1 No. of animals died: 1								
Species: Dog Breed/produ	^{uction type:} Spaniel - Springer English								
Sex/physiological status: female male pregnant neutered lactating other: Unknown									
Weight (kilos): Unknown Age: 6 Year(s)									
State of health at time of treatment: good fair poor critical unknown									
Reason(s) for treatment (prevention against what disease(s) or	or initial diagnosis):								
UNKNOWN									
6. PRODUCT DATA #1 Trade name (include dosage form and strength):	M.A. number: 42058/5031								
	Dogs; Dosage Form: Solution for injection								
Active substance(s) (INN): Bedinvetmab ATC vet code: QN02BG91									
Batch No.: REQUESTED, UNKNOWN Expiry date:UNKNOWN Storage details:UNKNOWN									
Treatment Details:UNKNOWN									
Dose/frequency:UNKNOWN	Route/site of administration: Unknown								
Start date of treatment: Stop date or duration									
9-Jan-2025 UNKNOWN	veterinarian owner other								
Use according to label: yes unknown no									
	educed other								
Did reaction abate after stopping drug? yes ☐ no									
Did reaction reappear after reintroduction? yes no									
List all other relevant medications given to animal(s):									
Product name/ Company	Batch No. Route and site of Dose, frequency, indication, duration of								
	admin treatment (dates of beginning and end)								

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SENDER REPORT IDENTIFICATION-CASE REF.No: Page 2 of 3 2025-UK-008510

Describe the sequence or events including administration of products, all clinical signs, site of maction, severity, pertinent lab test, necropsy results, possible contributing factors (if necessary use extra sheet): See confinuation page Adverse Events 25May25: A pet owner reported a suspected adverse reaction involving LIBRELA in a dog (6-year-old right) in Springer Spaniel, female, weight and condition was not provided), in 0.93 and 5 the dog was administered an unknown dose of LIBRELA. Indication and administered by are unknown. On the 10Jan25 she had multiple seizures and died. Vets suspicion is unknown. Freatment unknown. Case closed. Were the unexpected signs treated? If yes, give the details of treatment including product(s) used: Outcome of reaction to date: Were the unexpected signs treated? If yes, give the details of treatment including product(s) used: Outcome of reaction to date: Outcome of reaction to the suspect product? Outcome of reaction to the suspect pr							
Describe the sequence or events including administration of product(s), all clinical signs, site of reaction, severity, befinded lab tests, necropsy results, possible contributing factors (if necessary use extra sheet): Adverse Events See continuation page	7. REACTION	Date of	· -	9-Jan-2025			
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	SENDER REPORT IDENTIFICATION-CASE REF.No: 2025-UK-008510	Page 3 of 3
7. REACTION DATA (continued)		
Medical History		

Version: unapproved