VETERINARY PHARMACOVIGILANCE

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

DRAFT REPORT

SENDER REPORT IDENTIFICATION-CASE REF.No: 2025-UK-017965

Safety issues in animals ☒ in humans ☐
Lack of expected efficacy ☐
Withdrawal period issues ☐
Environmental problems ☐

Reporting country: United Kingdom
Purchase country: United Kingdom
Report source: Owner

1. ADDRESS OF COMPETENT AUTHORITY

[redacted]

2. NAME AND ADDRESS OF SENDER

[redacted]

Date complaint received by sender: 4-Nov-2025 (dd-Mon-yyyy)

Type of report Initial ☒ Follow-up ☐ (date, case number)

Person who reported the reaction : veterinarian ☐ owner ☒ physician ☐ pharmacist ☐ other:

3. VETERINARIAN/ PHYSICIAN/ PHARMACIST

[redacted]

4. ANIMAL OWNER / HUMAN PATIENT

[redacted]

5. ANIMAL DATA **No. of animals treated: 1** **No. of animals showing signs: 1** **No. of animals died: 1**

Animal characteristics (animal(s) showing signs):

Species: Dog Breed/ production type: Lhasa Apso

Sex/ physiological status: female ☒ male ☐ pregnant ☐ neutered ☐ lactating ☒ other:

Weight (kilos): 9.1 Age: 15 Year(s)

State of health at time of treatment: good ☐ fair ☐ poor ☐ critical ☐ unknown ☒

Reason(s) for treatment (prevention against what disease(s) or initial diagnosis):

--UNKNOWN--

6. PRODUCT DATA #1

Trade name (include dosage form and strength): M.A. number: 42058/5029

Librela 5 mg Solution for Injection for Dogs; Dosage Form: Solution for injection

Active substance(s) (INN): Bedinvetmab ATC vet code: QN02BG91

Batch No.: 756076 Expiry date: --UNKNOWN-- Storage details: --UNKNOWN--

Treatment Details: --UNKNOWN--

Dose/ frequency: 1 Vial per 1 Route/ site of administration: Unknown

Start date of treatment: 16-Sep-2025 Stop date or duration: --UNKNOWN-- Who administered the product: Veterinarian

veterinarian ☐ owner ☐ other ☒

Use according to label: yes ☒ unknown ☐ no ☐ explain: --UNKNOWN--

Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐

Did reaction abate after stopping drug? yes ☐ no ☐ not applicable ☐

Did reaction reappear after reintroduction? yes ☐ no ☐ not applicable ☐

List all other relevant medications given to animal(s):

Product name/	Company	Batch No.	Route and site of admin	Dose, frequency, indication, duration of treatment (dates of beginning and end)

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7. REACTION DATA

Date of onset of unexpected signs: 18-Sep-2025

Duration of reaction: 6 Day(s)

Describe the sequence or events including administration of product(s), all clinical signs, site of reaction, severity, pertinent lab tests, necropsy results, possible contributing factors (if necessary use extra sheet): *See continuation page*

Adverse Events

14OCT25: A pet owner reported an adverse reaction involving LIBRELA 5MG INJECTABLE in a dog (a 15year old, female, intact Lhasa Apso, weighing 9.1kgs in unknown condition at time of treatment.)
On 16sep25 she was administered LIBRELA 5MG INJECTABLE (756076) by the vet, for the indication of pain relief associated with osteoarthritis.
On approx 18sep25 she was reported to have a raging thirst, ataxia in her back legs. On approx 19sep25 she was lethargic and did not want to get up. She had weakness in her hind limbs and was not wanting to eat, not wanting to drink and was incontinent.

Were the unexpected signs treated? If yes, give the details of treatment including product(s) used:

Outcome of reaction to date:

	Killed/ euthanised	died	under treatment	alive with sequelae	recovered	unknown
No of animals:	0	1	0	0	0	0
Date when:		--UNKNOWN--				

8. ATTENDING VETERINARIAN'S LEVEL OF SUSPICION THAT DRUG CAUSED

possible ☐ unlikely ☐ no attending vet ☒

9. PREVIOUS EXPOSURE AND REACTION(S) TO PRODUCT(S)

Previous exposure to the suspect product? no ☒ yes ☐ Date(s):

Previous reaction to the suspect product? no ☐ yes ☐ Describe: --UNKNOWN--

De-challenge information: --UNKNOWN--

10. DETAILS OF SUSPECTED ADVERSE REACTION(S) IN HUMANS

Patient details Sex: --UNKNOWN-- Pregnant ☐ Age/ date of birth: --UNKNOWN-- Occupation (if relevant): --UNKNOWN--

Date of exposure: --UNKNOWN-- Date of reaction: --UNKNOWN--

Nature and duration of exposure, reaction details (including symptoms) and outcome:

--UNKNOWN--

[redacted]

[redacted]

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SENDER REPORT IDENTIFICATION-CASE REF.No:	Page 3 of 3
2025-UK-017965	

7. REACTION DATA (continued)

Adverse Events

The outcome is she died 24sep25. Treatment is unknown. No
attending vet. No further information.
CASE UPDATE 16OCT25; The lot number for LIBRELA was added to the product page.
SUPPLEMENTAL DOCUMENTS:
1.Other-FDA HL7 additional text
(Polydipsia, Ataxia, Lethargy, Recumbency, Muscle weakness, Anorexia, Adipsia, Urinary
incontinence, Death), [redacted]