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: 2025-UK-006553

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: 28-Apr-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: 0**

Animal characteristics (animal(s) showing signs):

Species: Dog
Breed/ production type: Terrier - Yorkshire
Sex/ physiological status: female ☐ male ☒ pregnant ☐ neutered ☐ lactating ☐ other: Unknown
Weight (kilos): 10
Age: 12 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.: REQUESTED, UNKNOWN
Expiry date: --UNKNOWN--
Storage details: --UNKNOWN--
Treatment Details: --UNKNOWN--

Dose/ frequency: --UNKNOWN--
Route/ site of administration: Unknown
Start date of treatment: 5-Dec-2024
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Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐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: 6-Feb-2025

Duration of reaction: --UNKNOWN--

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

07APR25: A pet owner reported a adverse reaction involving LIBRELA SOLUTION FOR INJECTION FOR DOGS in a canine (Yorkshire terrier, male, entire, 12 years old, 10kg in unknown condition). The patient has received Librela monthly since 05Sep24.
On 05DEC24 he was administered an unknown dose of Librela by the vet, for the indication of suspected arthritis. On 06FEB25 he developed tremors like someone has a stun gun against his body. Incontinence during the night. Anxiety and afraid like symptoms. Shakes when drinking water, slow breathing and chest like infection when sleeping. Unknown growths and head twitching. This was treated with Prednisolone and current outcome is unknown. No attending vet. No further

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	0	0	0	0	1
Date when:						

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): --UNKNOWN--

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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7. REACTION DATA (continued)

Adverse Events

information.
SUPPLEMENTAL DOCUMENTS:
[redacted]
(Tremor, Urinary incontinence, Anxiety, Tremor, Bradypnoea, Respiratory tract infection NOS, Tremor, Mass NOS), (Outcome : Unknown)

Medical History