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-000994

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: 14-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: Retriever - Labrador

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

Weight (kilos): 35.5 Age: 13 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 *See continuation page*

Trade name (include dosage form and strength): M.A. number: 42058/5032

Librela 20 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: 1 Vial per 1 Route/ site of administration: Unknown

Start date of treatment: 27-Dec-2024 Stop date or duration: --UNKNOWN-- Who administered the product: Unknown

veterinarian ☐ owner ☐ other ☒

Use according to label: yes ☐ unknown ☐ no ☒ explain: Treatment regimen Off-Label

Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐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)
Nobivac L4 Suspension for Injection for Dogs (Leptospira australis)	Intervet International B.V.	REQUESTED, UNKNOWN	Unknown	27-Dec-2024

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7. REACTION DATA

Date of onset of unexpected signs: 27-Dec-2024

Duration of reaction: 10 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

On 06Jan25 a pet owner reported a suspected adverse reaction in her dog (13-year-old male Labrador Retriever, weight and condition unknown) and LIBRELA SOLUTION FOR INJECTION FOR DOGS. On 27Dec24 the dog received a dose of LIBRELA SOLUTION FOR INJECTION FOR DOGS, (indication, dose and administered by are unknown). The pet owner reported that on 28Dec24 her dogs hind legs collapsed. One day after his monthly injection of Librela, his hind legs collapsed and still cannot get up. The outcome, treatment and vets suspicion are unknown. No further information is expected.
22Jan25 Follow up received from vet. The dog is 35.5 kg, treated with Librela 20MG, not at set

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	1	0	0	0
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:

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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6. PRODUCT DATA # 2

Trade name (include dosage form and strength): M.A. number: 01708/5048

Nobivac L4 Suspension for Injection for Dogs; Dosage Form: Suspension for injection

Active substance(s) (INN): Leptospira australis ATC vet code: QI07AB01

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: Who administered the product: Veterinarian

27-Dec-2024 --UNKNOWN-- veterinarian ☐ owner ☐ other ☒

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

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

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

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

Possible ☐ unlikely ☐ no attending vet ☐ --UNKNOWN--

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--

[redacted]

7. REACTION DATA (continued)

Adverse Events

intervals so off-label (treatment program not respected). Dates of Librela ere Nov23, Dec23, Jun24, Jul24, Sep24 and Oct24. On 27Dec24 the dog was also administered NOBIVAC L4. The owner told the vet the dog was on Gabapentin and Paracetamol at home as treatment, (not prescribed by the vet). The vet has not examined the dog since the event, but on 06Jan25 the owner told him the dog was slowly improving, getting up with assistance but wobbly. The vet could not rule out Librela, but was suspicious of other causes, but had not seen the dog to confirm this. No further information is expected.
11Apr25 follow up from the pet owner. They report the following clinical side effects, due to Librela: pacing, panting, confusion, uncoordinated, blankly staring, swollen limbs, projectile vomiting, excessive drinking, wobbly walking (ataxia), sudden collapses, cloudy eyes, .lesions, urinary and faecal incontinence, weight loss, lethargic, drooling, .non-stop crying, diarrhoea, passing blood (uncoded sign as it does not state where blood is coming from), liver damage, kidney damage and total loss of his hind legs. Outcome updated to remains under treatment. Case closed.
NCA comment- VeDDRA 'blood loss NOS' added for 'passing blood'.
(Collapse NOS, Ataxia, Cloudy eye, Renal disorder NOS, Involuntary defecation, Hepatopathy, Paresis, Hyperactivity, Disorientation, Urinary incontinence, Emesis, Weight loss, Oedema NOS, Skin lesion NOS, Lethargy, Vocalisation, Polydipsia, Hypersalivation, Recumbency, Tachypnoea, Impaired consciousness, Ataxia, Haemorrhage NOS, Diarrhoea), (Outcome : Remains under treatment)

Medical History

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