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: 2024-UK-014129

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: 21-Oct-2024 (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: Spaniel - Springer English

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

Weight (kilos): 20 Age: 11 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: 42058/5031

Librela 15 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: Subcutaneous

Start date of treatment: 27-Aug-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Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐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): *See continuation page*

Product name/	Company	Batch No.	Route and site of admin	Dose, frequency, indication, duration of treatment (dates of beginning and end)
gabapentin (gabapentin)	CoName - Unknown	requested, unknown	Unknown	9 Month(s) 3 Week(s), (1-Jan-2024 - 22-Oct-2024)
Pardale-V 400 mg/9 mg Tablets (Paracetamol)	Novacyl (WUXI) Pharmaceuti	requested, unknown	Unknown	1-Jan-2024

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7. REACTION DATA

Date of onset of unexpected signs: 2-Sep-2024

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

On the 29SEP24 a pet owner reported a suspected adverse reaction involving a canine (Springer spaniel, male, entire, 11 years, weight unknown and in fair condition prior to treatment) and LIBRELA SOLUTION FOR INJECTION FOR DOGS 15MG/ML for the treatment of pain relating to Osteoarthritis.
On the 27AUG24 he was administered his first vial of Librela subcutaneously by the attending vet. Concurrent medication includes Gabapentin, Tralieve and Pardale V.
On the 02SEP24 he became wobbly, collapsed, was falling over, and paralyzed on his hindlimbs. He was treated with Pain relief. On the 23SEP24 he was examined by a vet who advised monitoring of

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:	1	0	0	0	0	0
Date when:	--UNKNOWN--					

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):

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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6. PRODUCT DATA (continued)

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

Product name/ active substance	Company	Batch No.	Route and site of admin	Dose, frequency, indication, duration of treatment (dates of beginning and end)
Tralieve 80 mg Chewable Tablets for Dogs (Tramadol hydrochloride)	cal Co. Ltd. Zydus Lifesciences Limited	UNK	Unknown	9 Month(s) 3 Week(s), (1-Jan-2024 - 22-Oct-2024)

6. PRODUCT DATA # 2

Trade name (include dosage form and strength): gabapentin; Dosage Form: Term defined by submitter

M.A. number: Unknown

Active substance(s) (INN): gabapentin

ATC vet code: UNKNOWN

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: 1-Jan-2024

Stop date or duration: 22-Oct-2024

Who administered the product: 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]

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6. PRODUCT DATA # 3

Trade name (include dosage form and strength): Pardale-V 400 mg/9 mg Tablets; Dosage Form: Tablet

M.A. number: 50406/5027

Active substance(s) (INN): Paracetamol

ATC vet code: QN02BE71

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: 1-Jan-2024

Stop date or duration: --UNKNOWN--

Who administered the product: 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]

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6. PRODUCT DATA # 4

Trade name (include dosage form and strength): M.A. number: 50406/5011

Tralieve 80 mg Chewable Tablets for Dogs; Dosage Form: Chewable tablet

Active substance(s) (INN): Tramadol hydrochloride ATC vet code: QN02AX02

Batch No.: --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: Unknown

1-Jan-2024 22-Oct-2024 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

his quality of life as he wasnt doing well. No further information available and the current outcome is unknown. The vets suspicions are unknown.

FOLLOW-UP 22OCT24
The canine was euthanised on the 22OCT24, no further information available.

NCA comment 26 NOV 2024: Email from owner received describing additional clinical signs "my otherwise healthy 11 year old Springer spaniel had the Librela injection for osteoarthritis in his back leg, Just 2 days later he was completely paralysed in both hind legs and became both urine and faecal incontinent, He started panting very heavily and had an unquenchable thirst, He lost weight due to losing his appetite, Just 7 weeks after his one and only injection he was dead, I'm in no doubt that Librela killed my dog". VeDDRAs appetite loss, excessive thirst, faecal incontinence, panting, urinary incontinence, weight loss, and death by euthanasia added as case imported without death VeDDRA.

Follow up narrative received on the 23.12.24
Dechra comment 5 Dec 24: added Tralieve 80 mg to product screen as best guess.

NCA comment 09 MAY 2025, duplicate case identified, narrative states: A male-neutered 11 year old 20kg English Springer Spaniel canine was administered Librela [NCA selected Librela 10 mg Solution for Injection for Dogs] on 27 AUG 2024. Adverse event on 29 AUG 2024, paralysis, incontinence, suffering for 7 weeks. Died or death by euthanasia = 1 animal. No post mortem examination was performed. No further information expected. VeDDRA Pain NOS added.

Dechra Comment: Ended product dates accordingly. This case is closed.
(Ataxia, Loss of consciousness, Ataxia, Paralysis, Malaise, Death, Weight loss, Anorexia, Polydipsia, Urinary incontinence, Involuntary defecation, Tachypnoea, General pain), (Outcome : Euthanasia)

Medical History