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-006559

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: 1**

Animal characteristics (animal(s) showing signs):

Species: Dog Breed/ production type: Retriever - Labrador

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

Weight (kilos): 34 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 *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.: UNKNOWN Expiry date: --UNKNOWN-- Storage details: --UNKNOWN--

Treatment Details: --UNKNOWN--

Dose/ frequency: 2 Vial per 1 Route/ site of administration: Subcutaneous

Start date of treatment: 28-Dec-2023 Stop date or duration: --UNKNOWN--

Who administered the product: Unknown
veterinarian ☐ owner ☐ other ☒

Use according to label: yes ☐ unknown ☐ no ☒ explain: Overdosed

Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐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)
gabapentin (gabapentin)	CoName - Unknown	UNKNOWN	Oral	300 Milligram(s) per 1 (1-Dec-2023)
Onsior NS (Robenacoxib)	Elanco	UNKNOWN	Oral	40 Milligram(s) per 1 (1-Dec-2023)
YuMove Advanced 360	UNK	UNKNOWN	Oral	2 Tablet per 1 (1-Dec-2023)

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7. REACTION DATA

Date of onset of unexpected signs: 29-Dec-2023

Duration of reaction: 14 Month(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 the 05Apr25 a pet owner reported a suspected adverse event and lack of efficacy involving a canine (12 year old, female neutered, Labrador retriever weighing 34 kg and in unknown condition prior to starting treatment with the product) and Librela 20mg, given for unspecified reasons. Despite request, the lot number is unknown. On 28Dec23 the dog was administered 2 vials of Librela. Previously the dog had Librela monthly since 17May23. Other concomitant medications include Gabapentin 300mg administered 3 times daily by mouth by the owner, Onsior 40mg administered once daily by mouth by the owner. Yumove Advanced 260, 2 tablets administered daily by mouth by the owner. Date of start of administration approximated to 01Dec23 for all other

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): --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): gabapentin

M.A. number: Unknown

Active substance(s) (INN): gabapentin

ATC vet code: UNKNOWN

Batch No.: UNKNOWN

Expiry date: --UNKNOWN--

Storage details: --UNKNOWN--

Treatment details: --UNKNOWN--

Dose/ frequency: 300 Milligram(s) per 1

Route/ site of administration: Oral

Start date of treatment: 1-Dec-2023

Stop date or duration: --UNKNOWN--

Who administered the product: Animal Owner

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): Onsior NS

M.A. number: Unknown

Active substance(s) (INN): Robenacoxib

ATC vet code: QM01AH91

Batch No.: UNKNOWN

Expiry date: --UNKNOWN--

Storage details: --UNKNOWN--

Treatment details: --UNKNOWN--

Dose/ frequency: 40 Milligram(s) per 1

Route/ site of administration: Oral

Start date of treatment: 1-Dec-2023

Stop date or duration: --UNKNOWN--

Who administered the product: Animal Owner

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): YuMove Advanced 360

M.A. number:

Active substance(s) (INN):

ATC vet code: UNKNOWN

Batch No.: UNKNOWN

Expiry date: --UNKNOWN--

Storage details: --UNKNOWN--

Treatment details:

--UNKNOWN--

Dose/ frequency: 2 Tablet per 1

Route/ site of administration: Oral

Start date of treatment: 1-Dec-2023

Stop date or duration: --UNKNOWN--

Who administered the product: Animal Owner

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

concomitant medication as this was not specified. On 29Dec23 a fatty lump was noted. On 30Jan24 a worsening cough was noted. On 07Feb24 a blood test revealed raised ALT and laryngeal paralysis was confirmed. The dog was treated with Amantadine. The decision was made to discontinue Librela In Jan24. On 06Mar24 the dog was restless at night and tachypnoeic. The dog was treated with increased doses of Gabapentin. On 06APr24 the owner noted the dog deteriorated (VEDDRA malaise). The dog was bloated secondary to aerophagia. The owner noted that the following signs were oberseved during the time the dog was on Librela but no date was specified and has thus been approximated to 01Jan24 for these signs which include General lethargy,Urinary Incontinence, Potential lack of efficacy of Librela, Excessive thirst, Occasional diarrhoea unattributed to anything else, Dementia-like symptoms (VEDDRA Cognitive disorder).
No treatment was specified. Later that same day on 06Apr24 the dog was euthanised. The vets suspicion was not known. No further information available, but if received, the case will be updated.
(Lipoma, Cough, Elevated liver enzymes, Cranial nerve disorder, Hyperactivity, Tachypnoea, Malaise, Flatulence, bloating and distension, Behavioural disorder NOS, Death, Lethargy, Urinary incontinence, Lack of efficacy, Polydipsia, Diarrhoea, Cognitive disorder NOS), (Outcome : Euthanasia)

Medical History