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-023191

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: Attending veterinarian

1. ADDRESS OF COMPETENT AUTHORITY

[redacted]

2. NAME AND ADDRESS OF SENDER

[redacted]

Date complaint received by sender: 28-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: 0**

Animal characteristics (animal(s) showing signs):

Species: Dog Breed/ production type: Retriever - Labrador

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

Weight (kilos): 33.1 Age: 6.83 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: Subcutaneous

Start date of treatment: 7-Nov-2024 Stop date or duration: 24-Jul-2025 Who administered the product: Veterinarian

veterinarian ☐ owner ☐ other ☒

Use according to label: yes ☐ unknown ☐ no ☒ explain: Indication 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Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐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): *See continuation page*

Product name/	Company	Batch No.	Route and site of admin	Dose, frequency, indication, duration of treatment (dates of beginning and end)
Metacam NS (Meloxicam)	CoName - Boehringer Ingelheim Animal Health UK Ltd	REQUESTED, UNKNOWN	Unknown	1-Jan-2024

VETERINARY PHARMACOVIGILANCE

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DRAFT REPORT

7. REACTION DATA

Date of onset of unexpected signs: 10-Oct-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

07NOV25: A vet nurse reported a suspected adverse reaction involving LIBRELA in a dog (6.83-years-old female neutered Labrador, 33.1 kg in unknown condition). Concurrent medication: Metacam, Paracetamol, Gabapentin.
On 07NOV24 the dog was started on LIBRELA 20MG, administered monthly by the vet for lameness Left shoulder. Most recent dose on 24JUL25.
On approx 01JAN25 she developed sudden onset lameness in her left hindlimb an some effusion on the left stifle. The vet suspects rapid progressive osteoarthritis
On approx 24OCT25 she developed right hind lameness, a potential cranial cruciate rupture, and

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 ☐ --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]

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-023191

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)
paracetamol NS (Paracetamol)	CoName - Unknown	REQUESTED, UNKNOWN	Unknown	1-Jan-2024
gabapentin NS (gabapentin)	CoName - Unknown	requested, unknown	Unknown	1-Jan-2024

6. PRODUCT DATA # 2

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

M.A. number: Unknown

Active substance(s) (INN): Meloxicam

ATC vet code: QM01AC06

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]

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:	Page 4 of 6
2025-UK-023191	

6. PRODUCT DATA # 3

Trade name (include dosage form and strength): M.A. number: Unknown

paracetamol NS; Dosage Form: Term defined by submitter

Active substance(s) (INN): Paracetamol ATC vet code: QN02BE01

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

1-Jan-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]

VETERINARY PHARMACOVIGILANCE

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

DRAFT REPORT

6. PRODUCT DATA # 4

Trade name (include dosage form and strength): M.A. number: Unknown

gabapentin NS; Dosage Form: Term defined by submitter

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: Stop date or duration: Who administered the product: Unknown

1-Jan-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

effusion.
Outcome under treatment, (details unknown). Vets suspicion not given. No further information.

Update 13JAN26: Librela was discontinued after last dose on 24JUL25 as vet worried about RPOA (Rapidly progressing osteoarthritis). On 10OCT25 the dog presented with lameness on the right hind, after playing in the park. 24OCT25 radiographs showed joint effusion consistent with cranial cruciate ligament rupture/ insufficiency. The left stifle view shows excessive peri-articular remodelling, and stifle effusion. 26NOV25 the dog was referred for imaging at a veterinary orthopedic specialists. Referral report: Left Stifle: Large amounts of periarticular new bone were evident with multiple areas of soft tissue mineralisation. The tibia was displaced cranially relative to the femur. In addition, irregular new bone formation, subchondral lucencies and flattening of the medial femoral condyle was evident. A very large synovial fusion was also present. Joint taps of both stifles revealed large volumes of grossly normal synovia fluid. In house cytology was unremarkable.
Right Stifle: A large effusion was evident with the presence of mild osteoarthritis. Forelimbs: Radiographs of all joints on the forelimbs were unremarkable. Hocks: Unremarkable. Diagnosis: Right stifle cranial cruciate ligament rupture with mild secondary osteoarthritis.
Left stifle cranial cruciate ligament rupture. Consider a musculoskeletal adverse effect to Librela with secondary RPOA. The dog had Tibial Plateau Leveling Osteotomy surgery to the right stifle to stabilise it. Prognosis for left hindlimb is unknown. Updated veddra codes and dates to align with clinical history. Outcome: under treatment. No further information.

30JAN26: following a request fromthe VMD, please note - on 13JAN26 the MAH received the clinical notes from the vets and the dates of the Veddra codes dates were updated to align with the new

information. In addition, the route of administration was updated from unknown, to subcutaneously.
(Arthritis, Bone and joint disorder NOS, Abnormal radiograph finding, Lameness, Arthritis, Ligament rupture), (Outcome : Remains under treatment)

Medical History