

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-008504 Page 1 of 3

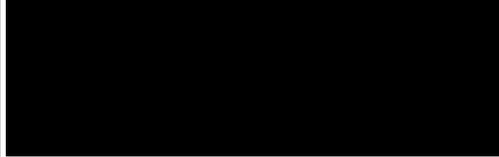
Safety issues in animals in humans
Lack of expected efficacy
Withdrawal period issues
Environmental problems

Reporting country: United Kingdom
Purchase country: United Kingdom
Report source: Owner

1. ADDRESS OF COMPETENT AUTHORITY



2. NAME AND ADDRESS OF SENDER

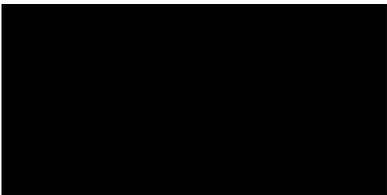


Date complaint received by sender: 2-Jun-2025
(dd-Mon-yyyy)

Type of report Initial Follow-up (date, case number)

Person who reported the reaction : veterinarian owner physician pharmacist other:

3. VETERINARIAN/ PHYSICIAN/ PHARMACIST



4. ANIMAL OWNER / HUMAN PATIENT



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): 42

Age: 2 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.: 738337

Expiry date: Oct-2025

Storage details: --UNKNOWN--

Treatment Details: --UNKNOWN--

Dose/frequency: 1 Vial per 1

Route/site of administration: Subcutaneous

Start date of treatment:

Stop date or duration:

Who administered the product: Veterinarian

27-Jan-2025

--UNKNOWN--

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Action taken after reaction: drug withdrawn dose reduced other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):

Product name/	Company	Batch No.	Route and site of admin	Dose, frequency, indication, duration of treatment (dates of beginning and end)
METACAM: BI (meloxicam)	UNK	REQUESTE D, UNKNOWN	Unknown	2-Dec-2024 - 10-Feb-2025

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-008504	Page 2 of 3
---	-------------

7. REACTION DATA Date of onset of unexpected signs: 8-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

12May25: A pet owner reported a suspected adverse reaction involving LIBRELA in a dog (2-year-old female neutered Labrador, 42 kg in fair condition). The dog was diagnosed with Bilateral cruciate disease, Hip dysplasia, Elbow dysplasia and Achilles tendonitis RH. She had bilateral TTA surgery for cruciate disease. The following product(s) were administered concomitantly: METACAM.

The dog was started on Librela on 11Oct23 at the age of 1 year and 2 months, for bilateral elbow dysplasia (off-label indication), administered monthly thereafter.

On 27Jan25 the dog was administered 1 x LIBRELA SOLUTION FOR INJECTION FOR DOGS 20 mg, (batch

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--

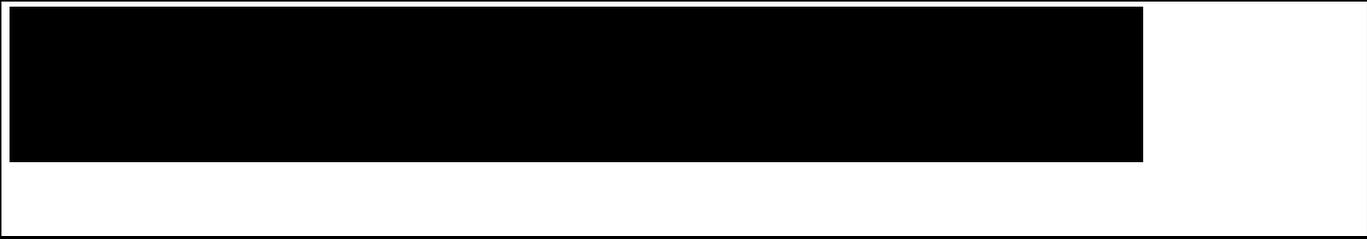
10. DETAILS OF SUSPECTED ADVERSE REACTION(S) IN HUMANS

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--



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-008504	Page 3 of 3
--	-------------

6. PRODUCT DATA # 2

Trade name (include dosage form and strength): METACAM: BI M.A. number:
Active substance(s) (INN): meloxicam ATC vet code: UNKNOWN
Batch No.: REQUESTED, UNKNOWN Expiry date: --UNKNOWN-- Storage details: --UNKNOWN--
Treatment details:
--UNKNOWN--

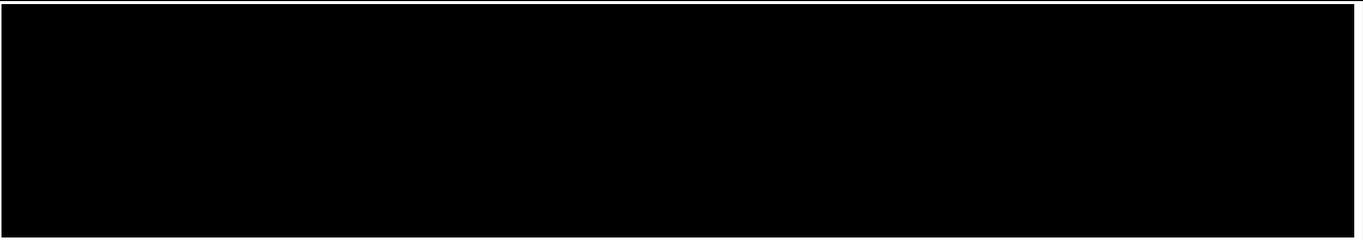
Dose/frequency: --UNKNOWN-- Route/site of administration: Unknown
Start date of treatment: 2-Dec-2024 Stop date or duration: 10-Feb-2025 Who administered the product: Unknown
veterinarian owner other
Use according to label: yes unknown no explain: --UNKNOWN--
Did reaction abate after stopping drug? yes 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--



7. REACTION DATA (continued)

Adverse Events

738337). On 08Feb25 the dog presented with lameness, identified as due to a fracture of the lateral condyle of the right elbow. On 10Feb25 she was euthanised. Vets suspicion and treatment are unknown. Case closed.

SUPPLEMENTAL DOCUMENTS:

1.0ther-FDA HL7 additional text
(Fracture, Death, Lameness), (Outcome : Euthanasia)

Medical History