

VETERINARY PHARMACOVIGILANCE

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

DRAFT REPORT

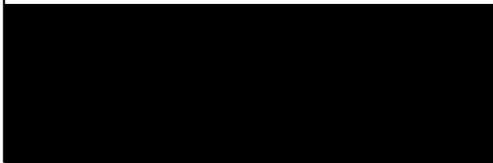
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Safety issues in animals in humans
Lack of expected efficacy
Withdrawal period issues
Environmental problems

Reporting country: United Kingdom
Purchase country: United Kingdom
Report source: Attending veterinarian

1. ADDRESS OF COMPETENT AUTHORITY

2. NAME AND ADDRESS OF SENDER



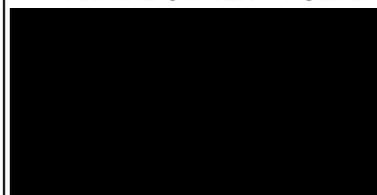
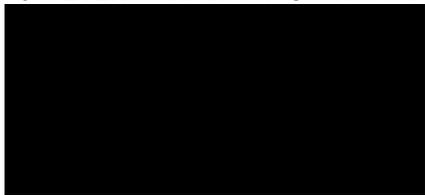
Date complaint received by sender: 28-Nov-2025
(dd-Mon-yyyy)

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

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

3. VETERINARIAN/ PHYSICIAN/ PHARMACIST

4. ANIMAL OWNER / HUMAN PATIENT



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: Unknown
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

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7. REACTION DATA Date of onset of unexpected signs: 1-Jan-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:

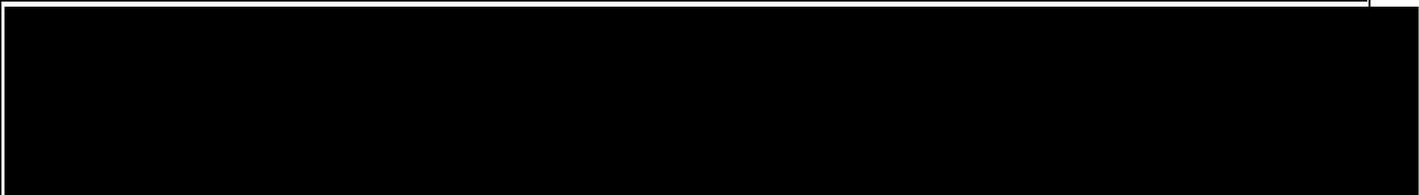
Outcome of reaction to date:

	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--



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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)
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):

M.A. number: Unknown

Metacam NS; Dosage Form: Term defined by submitter

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:

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

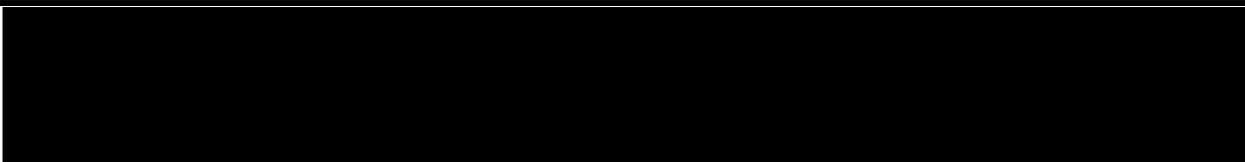
Possible unlikely no attending vet --UNKNOWN--

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--



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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--

7. REACTION DATA (continued)

Adverse Events

effusion.

Outcome under treatment, (details unknown). Vets suspicion not given. No further information. (Arthritis, Bone and joint disorder NOS, Abnormal radiograph finding, Lameness, Arthritis, Ligament rupture), (Outcome : Remains under treatment)

Medical History