

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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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--



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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 # 3

Trade name (include dosage form and strength): paracetamol NS; Dosage Form: Term defined by submitter M.A. number: Unknown
Active substance(s) (INN): Paracetamol ATC vet code: QN02BE01
Batch No.: REQUESTED, UNKNOWN Expiry date: --UNKNOWN-- Storage details: --UNKNOWN--
Treatment details:
--UNKNOWN--

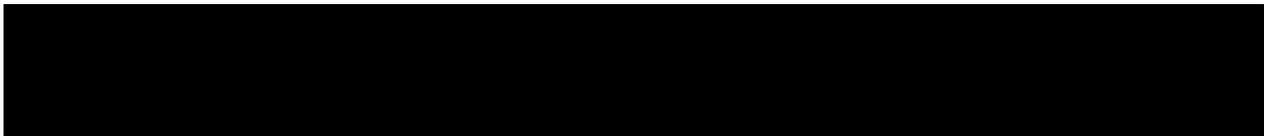
Dose/frequency: --UNKNOWN-- Route/site of administration: Unknown
Start date of treatment: 1-Jan-2024 Stop date or duration: --UNKNOWN-- Who administered the product: Veterinarian
veterinarian owner other
Use according to label: yes unknown no explain: --UNKNOWN--
Did reaction abate after stopping drug? 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

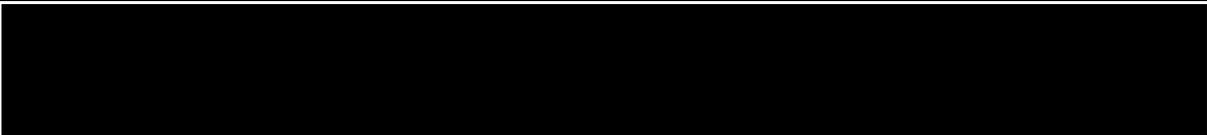
Trade name (include dosage form and strength): gabapentin NS; Dosage Form: Term defined by submitter M.A. number: Unknown
Active substance(s) (INN): gabapentin ATC vet code: UNKNOWN
Batch No.: requested, unknown Expiry date: --UNKNOWN-- Storage details: --UNKNOWN--
Treatment details:
--UNKNOWN--
Dose/frequency: --UNKNOWN-- Route/site of administration: Unknown
Start date of treatment: 1-Jan-2024 Stop date or duration: --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--



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 from the 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

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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