

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: Owner
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1. ADDRESS OF COMPETENT AUTHORITY	2. NAME AND ADDRESS OF SENDER

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	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): 34 Age: 13 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: Stop date or duration: Who administered the product: Unknown

28-Dec-2023 --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Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐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): See continuation page

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)
paracetamol NS (Paracetamol)	CoName - Unknown	UNKNOWN	Oral	250 Milligram(s) per 1 (1-Dec-2023)
Rimadyl Palatable Tablets for Dogs 50 mg (Carprofen)	Erregierre S.P.A.	UNKNOWN	Oral	1.5 Tablet per 1 (1-Dec-2023)

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7. REACTION DATA

Date of onset of unexpected signs: 28-Dec-2023

Duration of reaction: 4 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 involving a canine (13 year old, female neutered, Labrador retriever weighing 34 kg and in unknown condition prior to starting treatment with the products) and Librela 20mg, Rimadyl 50mg and Apoquel 16mg given for unspecified reasons. Despite request, the lot number of each product is unknown. On 28Dec23 the dog was administered 2 vials of Librela. Previously the dog had Librela monthly since 17May23. The dog was also taking Rimadyl 50mg tablets at a dose of 1.5 tablets daily by mouth administered by the pet owner. Date of start of administration approximated to 01Dec23 as this was not specified. In addition the dog was taking Apoquel 16mg tablets once daily administered by mouth

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 --

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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)
YuMove Advanced 360	UNK	UNKNOWN	Oral	2 Tablet per 1 (1-Dec-2023)
Apoquel 16mg Film-coated Tablet for Dogs (Oclacitinib)	Zoetis Belgium SA	UNKNOWN	Oral	1 Tablet per 1 (1-Dec-2023)
chlorpheniramine/chlorphenam ine NS	UNK	UNKNOWN	Oral	8 Milligram(s) per 1 (1-Dec- 2023)

6. PRODUCT DATA # 2

Trade name (include dosage form and strength):

M.A. number: Unknown

gabapentin

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:

Stop date or duration:

Who administered the product: Animal Owner

1-Dec-2023

--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	M.A. number: Unknown
Active substance(s) (INN): Paracetamol	ATC vet code: QN02BE01
Batch No.: UNKNOWN	Expiry date: --UNKNOWN--
Storage details: --UNKNOWN--	
Treatment details: --UNKNOWN--	
Dose/frequency: 250 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--			

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6. PRODUCT DATA # 4

Trade name (include dosage form and strength): Rimadyl Palatable Tablets for Dogs 50 mg; Dosage Form: Tablet M.A. number: 42058/5168

Active substance(s) (INN): Carprofen ATC vet code: QM01AE91

Batch No.: UNKNOWN Expiry date: --UNKNOWN-- Storage details: --UNKNOWN--

Treatment details:
--UNKNOWN--

Dose/frequency: 1.5 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

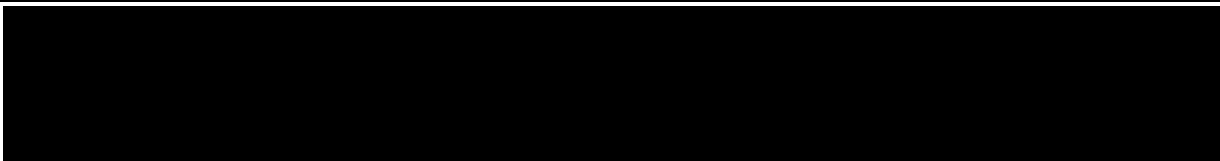
Possible ☐ unlikely ☐ no attending vet ☐ --UNKNOWN--

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--



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6. PRODUCT DATA # 5

Trade name (include dosage form and strength):

M.A. number:

YuMove Advanced 360

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:

Stop date or duration:

Who administered the product: Animal Owner

1-Dec-2023

--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 # 6

Trade name (include dosage form and strength):		M.A. number: 42058/5005
Apoquel 16mg Film-coated Tablet for Dogs; Dosage Form: Tablet, film coated		
Active substance(s) (INN): Oclacitinib		ATC vet code: QD11AH90
Batch No.: UNKNOWN	Expiry date: --UNKNOWN--	Storage details: --UNKNOWN--
Treatment details: --UNKNOWN--		
Dose/frequency: 1 Tablet per 1		Route/site of administration: Oral
Start date of treatment:	Stop date or duration:	Who administered the product: Animal Owner
1-Dec-2023	--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 # 7

Trade name (include dosage form and strength):

M.A. number:

chlorpheniramine/chlorphenamine NS

Active substance(s) (INN):

ATC vet code: UNKNOWN

Batch No.: UNKNOWN

Expiry date: --UNKNOWN--

Storage details: --UNKNOWN--

Treatment details:

--UNKNOWN--

Dose/frequency: 8 Milligram(s) per 1

Route/site of administration: Oral

Start date of treatment:

Stop date or duration:

Who administered the product: Animal Owner

1-Dec-2023

--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

by the owner. Date of start of administration approximated to 01Dec23 as this was not specified. Other concomitant medications include Gabapentin 300mg administered 3 times daily by mouth by the owner, Paracetamol 250mg administered 3 times daily by mouth by the owner. Yumove Advanced 260, 2 tablets administered daily by mouth by the owner, and Piriton 8mg administered twice daily by mouth by the owner. Date of start of administration approximated to 01Dec23 for all other concomitant medication as this was not specified. On 05Jan24 forelimb lameness was noted accompanied by development of a visible lump on the limb (VEDDRA Mass NOS). On 30Jan24 on going coughing was noted, this had been noted previously while having Librela 20mg. The owner commented that throughout the time in which Librela was being administered, as well as shortly after, I noticed the following other side effects, General lethargy, Potential lack of efficacy of Librela, Excessive thirst, Occasional diarrhoea unattributed to anything else and halitosis dates have been approximated to 05Jan24 for these signs. The decision was made to discontinue Librela In Jan24. On 07Feb24 the dog was Tested for Laryngeal Paralysis, outcome unknown. Radiographs showed continued complications, however assumed to be due to arthritis.

On 01May24 the owner noted the dog deteriorated (VEDDRA malaise). No treatment was specified. On 04May24 the dog was euthanised. The vets suspicion was not known. No further information available, but if received, the case will be updated.

(Lameness, Mass NOS, Cough, Lethargy, Lack of efficacy, Polydipsia, Diarrhoea, Halitosis, Malaise, Death, Arthritis, Overdose, Abnormal radiograph finding), (Outcome : Euthanasia)

Medical History