

# 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 <input checked="" type="checkbox"/> in humans <input type="checkbox"/> Lack of expected efficacy <input type="checkbox"/> Withdrawal period issues <input type="checkbox"/> Environmental problems <input type="checkbox"/>	Reporting country: United Kingdom Purchase country: United Kingdom Report source: Owner
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<b>1. ADDRESS OF COMPETENT AUTHORITY</b> [Redacted]	<b>2. NAME AND ADDRESS OF SENDER</b> [Redacted]
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Date complaint received by sender: --UNKNOWN--  
(dd-Mon-yyyy)  
Type of report Initial  Follow-up  (date, case number)  
Person who reported the reaction : veterinarian  owner  physician  pharmacist  other:

<b>3. VETERINARIAN/ PHYSICIAN/ PHARMACIST</b> [Redacted]	<b>4. ANIMAL OWNER / HUMAN PATIENT</b> [Redacted]
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**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: Spaniel - Springer English  
Sex/physiological status: female  male  pregnant  neutered  lactating  other:  
Weight (kilos): 20 Age: 11 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**  
Trade name (include dosage form and strength): M.A. number: 42058/5030  
Librela 10 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: --UNKNOWN-- Route/site of administration: --UNKNOWN--  
Start date of treatment: 27-Aug-2024 Stop date or duration: 28-Aug-2024 Who administered the product: Veterinarian  
veterinarian  owner  other   
Use according to label: yes  unknown  no  explain: --UNKNOWN--  
Action taken after reaction: drug withdrawn  dose reduced  other   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)

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**7. REACTION DATA**      Date of onset of unexpected signs: 29-Aug-2024  
 Duration of reaction: 7 Week(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

A male-neutered 11 year old 20kg English Springer Spaniel canine was administered Librela [NCA selected Librela 10 mg Solution for Injection for Dogs] on 27 AUG 2024. Adverse event on 29 AUG 2024, paralysis, incontinence, suffering for 7 weeks. The dog died despite treatment being administered. No post mortem examination was performed. No further information expected. (Urinary incontinence, General pain, Death, Paralysis), (Outcome : Unknown)

Medical History

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	1	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):

Previous reaction to the suspect product?    no     yes     Describe: -- UNKNOWN --

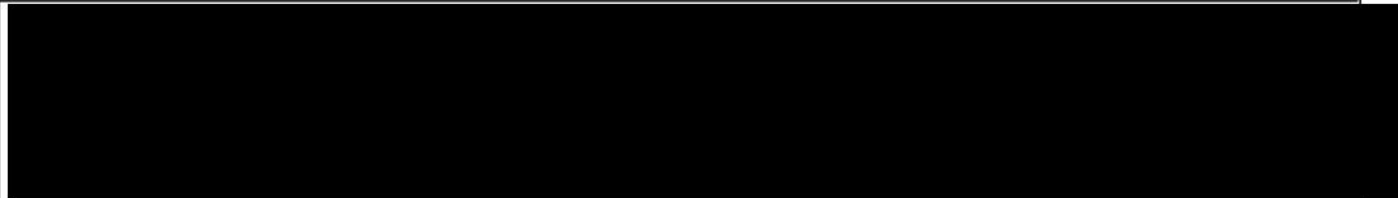
De-challenge information: -- UNKNOWN --

**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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7. REACTION DATA (continued)