

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-001093 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
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1. ADDRESS OF COMPETENT AUTHORITY	2. NAME AND ADDRESS OF SENDER
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Date complaint received by sender: 28-Jan-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
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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: Cat Breed/production type: Domestic Shorthair

Sex/physiological status: female ☒ male ☐ pregnant ☐ neutered ☒ lactating ☐ other:

Weight (kilos): 4 * 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: 42058/5004

Solensia 7 mg/ml Solution for Injection for Cats; Dosage Form: Solution for injection

Active substance(s) (INN): Frunevetmab ATC vet code: QN02BG90

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

Treatment Details: --UNKNOWN--

Dose/frequency: 1 Vial per 1 Route/site of administration: Subcutaneous

Start date of treatment: 29-Jun-2023 Stop date or duration: --UNKNOWN-- 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Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐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):

Product name/	Company	Batch No.	Route and site of admin	Dose, frequency, indication, duration of treatment (dates of beginning and end)
meloxicam NS (Meloxicam)	CoName - Unknown	UNK	Unknown	28-Apr-2023 - 3-Jul-2023

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7. REACTION DATA

Date of onset of unexpected signs: 29-Jun-2023

Duration of reaction: 4 Day(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 07Jan25 a pet owner reported a suspected adverse reaction involving their cat, (a 13-year-old female neutered domestic shorthair, approx. 4 kg in fair condition) and SOLENSIA 7 MG/ML SOLUTION FOR INJECTION FOR CATS. She had a long standing heart murmur, a history of feline asthma and vaccines reactions as a young cat (details not provided).

On 29Jun23 the vet administered 1 x vial of SOLENSIA 7 MG/ML SOLUTION FOR INJECTION FOR CATS for treatment of pain associated with a torn ligament (off-label - indication). The cat was already on meloxicam, start date 28Apr23. The owner reported that the cat became ataxic on her hindlimbs and was glazed over/vacant, staring/unresponsive (Veddra PT- Impaired consciousness).

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:	3-Jul-2023					

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 # 2

Trade name (include dosage form and strength):

M.A. number: Unknown

meloxicam NS

Active substance(s) (INN): Meloxicam

ATC vet code: QM01AC06

Batch No.: --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

28-Apr-2023

3-Jul-2023

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 ☐

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

03Jul23 the cat presented as not eaten since Solensia was administered, lethargic, quiet and vomiting overnight. On clinical examination the cat was pale, lethargic, heart murmur (pre-existing), hyperpnoea and dehydrated. Bloods showed a mild neutrophilia and renal disease, elevated creatinine, urea and also amylase and total proteins. Radiographs show the kidneys appear slightly larger. Phosphorus was high and potassium was low. The cat was euthanised due to the poor prognosis. The pet owner believes Solensia was the cause of her cats death. No further information is expected.

(Death, Anorexia, Lethargy, Pale mucous membrane, Dyspnoea, Dehydration, Hyperphosphataemia, Neutrophilia, Renal insufficiency, Abnormal radiograph finding, Emesis, Hypokalaemia, Ataxia, Impaired consciousness, Loss of consciousness, Elevated pancreatic enzymes, Hyperalbuminaemia, Increased blood urea nitrogen (BUN) or creatinine, Increased blood urea nitrogen (BUN) or creatinine), (Outcome : Euthanasia)

Medical History