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-015362

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

[redacted]

2. NAME AND ADDRESS OF SENDER

[redacted]

Date complaint received by sender: 22-Sep-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

[redacted]

4. ANIMAL OWNER / HUMAN PATIENT

[redacted]

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: Cat
Breed/ production type: Abyssinian Cat
Sex/ physiological status: female ☒ male ☐ pregnant ☐ neutered ☒ lactating ☐ other:
Weight (kilos): 2.3
Age: 19 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: 42058/5004
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: 7-Jul-2025
Stop date or duration: 5-Sep-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Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐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):

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: 10-Sep-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

19SEP25: A vet reported a suspected adverse reaction involving SOLENSIA in a cat (19-year-old female neutered Abyssinian, 2.3 kg in poor condition). Severe chronic renal failure and anaemia, on a renal diet but no medications. Pre-Solensia the cat was described as having a skin tent and muscle atrophy with a body condition score of 2 out of 5.
On 07JUL25 the cat was started on 1 x vial of SOLENSIA for osteoarthritis, administered monthly subcutaneously by the vet. (off-label indication. As per the SPC Do not use in animals under 2.5 kg body weight- Note it was given deliberately). Most recent dose of Solensia was administered on 05SEP25.

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 ☐

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--

[redacted]

[redacted]

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7. REACTION DATA (continued)

Adverse Events

On 13SEP25 the cat presented unwell with recent 300g weight loss in a week, 3-day history of diarrhoea, wobbly and urinating twice daily. Investigations were offered to the owner, who declined as they opted for palliative care due to the cats age and condition. Treated with buprenorphine, mirtazapine, and subcutaneous fluids. Outcome is under treatment. Vet could not rule out the role of the product. No further information is expected.

23-SEP-2025 NCA Comment: Additional information was received from a veterinary surgeon. The date of the second dose was reported as 04-AUG-2025. The cat was reported by the owner as being possibly polydipsic when presented on 13-SEP-2025. The cat's body condition score on this day was 1.5/5 and she was described as bright, alert and responsive but wobbly with some periodontal disease and missing teeth, alongside a skin tent, tachycardia (+200 bpm with gallop rhythm) and slight abdominal effort. The kidneys were possibly small on palpation. VeDDRA LLTs Tachycardia, Arrhythmia, Tooth loss, Dental disease, Renal disorder NOS, Decreased skin turgor, Polydipsia and Abnormal breathing. No further information is expected.
(Diarrhoea, Weight loss, Ataxia, Polyuria/pollakiuria, Malaise, Gingival disorder, Dehydration, Tachycardia, Renal disorder NOS, Arrhythmia, Tooth disorder, Polydipsia, Dyspnoea), (Outcome : Remains under treatment)

Medical History