

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-023264 Page 1 of 4

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

Date complaint received by sender: 1-Dec-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: 0

Animal characteristics (animal(s) showing signs):

Species: Cat Breed/production type: Domestic Shorthair

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

Weight (kilos): 5.08 Age: 16 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):
osteoarthritis pain

6. PRODUCT DATA #1 See continuation page

Trade name (include dosage form and strength): Solensia 7 mg/ml Solution for Injection for Cats; Dosage Form: Solution for injection M.A. number: 42058/5004

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

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

Treatment Details: osteoarthritis pain

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

Start date of treatment: 8-Sep-2025 Stop date or duration: 15-Oct-2025 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Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐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)
prednisolone NS (Prednisolone)	CoName - Unknown	UNK	Unknown	2.5 mg per day, IBS, (8-Sep-2025)

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SENDER REPORT IDENTIFICATION-CASE REF.No: 2025-UK-023264 Page 2 of 4

7. REACTION DATA

Date of onset of unexpected signs: 16-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

10NOV25: A vet reported an adverse event involving Solensia in a feline (Domestic short hair, male neutered, 16yrs, 5.08kg, good health prior to the product).
On 08SEP25, Solensia was administered by the veterinary surgeon for the indication of osteoarthritis. Monthly doses continued with the most recent given on 15OCT25.
On 16OCT25, he exhibited weakness in one hind limb and began defaecating outside of the litter box. No treatment was given. Outcome is currently unknown.
Attending vets level of suspicion is possible product association.

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--

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DRAFT REPORT

SENDER REPORT IDENTIFICATION-CASE REF.No:
2025-UK-023264

Page 3 of 4

6. PRODUCT DATA # 2

Trade name (include dosage form and strength):

M.A. number: Unknown

prednisolone NS; Dosage Form: Tablet

Active substance(s) (INN): Prednisolone

ATC vet code: QH02AB06

Batch No.: --UNKNOWN--

Expiry date: --UNKNOWN--

Storage details: --UNKNOWN--

Treatment details:

IBS

Dose/frequency: 2.5 mg per day

Route/site of administration: Unknown

Start date of treatment:

Stop date or duration:

Who administered the product: Unknown

8-Sep-2025

Ongoing

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

FOLLOW UP 12DEC25: Further information received. The vet reported that he has confirmed ataxia of the hind limbs. Referral was offered to the client but at this stage has been declined. No further information expected.

FOLLOW UP 12DEC25: Blood results showed low reticulocytes, low glucose and low gamma glutamyl transferase (Coded: Other abnormal test). No further information is expected.

FOLLOW UP 09FEB26: Further information received, difficulty of jumping up higher than a chair and struggling a bit up stairs after first injection; but after about 3-4 weeks I noticed he was a bit 'clumsy'. Proceeded with second injection and slowly he became worse: hindquarters very uncoordinated, tripping over himself, unable to jump up to previous heights or onto anything at all really, could get onto low sofa but had to 'claw' himself up with front paws. Coming down stairs he would 'bunny hop' and often collapse at the bottom. Would also collapse on the left hind side just when walking, which was odd given originally the bad side was the left. Would have to sit after walking a short distance. Became very easily startled, and he stopped cleaning himself. Was having litter box problems, pooping and sometimes urinating outside the box. We had to buy a special low entry-way box for disabled cats. There is now perhaps a 5 percent improvement but he still has ataxia and most of the above symptoms. No further information is expected.

NCA comment 17/02/2026: Further information received from the reporter. Concurrent products: Prednisolone, 2.5 mg per day for IBS. Immediate treatment: Solensia was stopped, now has red light therapy and on Lions Mane and Antinol since mid-November. VeDDRA LLTs 'Clumsy' and 'Incoordination' added as per narrative. Reaction figures changed from Unknown: 1/Ongoing: 0 to Unknown: 0/ Ongoing: 1. No further information is expected.

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SENDER REPORT IDENTIFICATION-CASE REF.No: 2025-UK-023264	Page 4 of 4
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(Muscle weakness, Inappropriate defecation, Ataxia, Decreased percentage of reticulocytes, Hypoglycaemia, Other abnormal test result NOS, Collapse NOS, Musculoskeletal disorder NOS, Inappropriate urination, Musculoskeletal disorder NOS, Behavioural disorder NOS, Ataxia, Ataxia),
(Outcome : Remains under treatment)

Medical History