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-018217

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: Other

1. ADDRESS OF COMPETENT AUTHORITY

[redacted]

2. NAME AND ADDRESS OF SENDER

[redacted]

Date complaint received by sender: 7-Nov-2025 (dd-Mon-yyyy)

Type of report Initial ☒ Follow-up ☐ (date, case number)

Person who reported the reaction : veterinarian ☐ owner ☐ physician ☐ pharmacist ☐ other: 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: 1**

Animal characteristics (animal(s) showing signs):

Species: Dog
Breed/ production type: Collie - Border
Sex/ physiological status: female ☒ male ☐ pregnant ☒ neutered ☐ lactating ☐ other:
Weight (kilos): 17.3
Age: 9 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: 05653/5040
Alizin 30 mg/ml Solution for Injection for dogs; Dosage Form: Solution for injection
Active substance(s) (INN): Aglepristone
ATC vet code: QG03XB90
Batch No.: Unknown
Expiry date: --UNKNOWN--
Storage details: --UNKNOWN--
Treatment Details: --UNKNOWN--

Dose/ frequency: 5.7 Milliliter per 1
Route/ site of administration: Subcutaneous
Start date of treatment: 13-Oct-2025
Stop date or duration: --UNKNOWN--
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Action taken after reaction: drug withdrawn ☐ dose reduced ☐ other ☐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: 14-Oct-2025

Duration of reaction: 1 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

9yr old entire female border collie mated last weekend (3rd/4th October), out of season this week, given first dose of alizin 10am yesterday (5.7ml given over two injection sites in scruff of neck), fine in self, clinical exam at the time NAD, lives in a kennel at home, checked at 5pm last night was fine in self. This morning owner found the dog dead in the kennel.

23rd October follow up- Spoken to practice in house post mortem revealed uterine bleed and abdominal full of blood.
(Death, Necropsy performed, Abdominal cavity haemorrhage, Uterine haemorrhage), [redacted]

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--

[redacted]

[redacted]

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7. REACTION DATA (continued)

[redacted]

Medical History