

# 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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|  |  |
|--|--|
| <p>Safety issues in animals <input checked="" type="checkbox"/> in humans <input type="checkbox"/></p> <p>Lack of expected efficacy <input type="checkbox"/></p> <p>Withdrawal period issues <input type="checkbox"/></p> <p>Environmental problems <input type="checkbox"/></p> | <p>Reporting country: United Kingdom</p> <p>Purchase country: United Kingdom</p> <p>Report source: Other</p> |
|--|--|

|   |   |
|---|---|
| <p><b>1. ADDRESS OF COMPETENT AUTHORITY</b></p> <div style="background-color: black; height: 60px; width: 100%;"></div> | <p><b>2. NAME AND ADDRESS OF SENDER</b></p> <div style="background-color: black; height: 60px; width: 100%;"></div> |
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**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

|  |   |
|--|---|
| <p><b>3. VETERINARIAN/ PHYSICIAN/ PHARMACIST</b></p> <div style="background-color: black; height: 60px; width: 100%;"></div> | <p><b>4. ANIMAL OWNER / HUMAN PATIENT</b></p> <div style="background-color: black; height: 60px; width: 100%;"></div> |
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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: 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): Alizin 30 mg/ml Solution for Injection for dogs; Dosage Form: Solution for injection M.A. number: 05653/5040

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

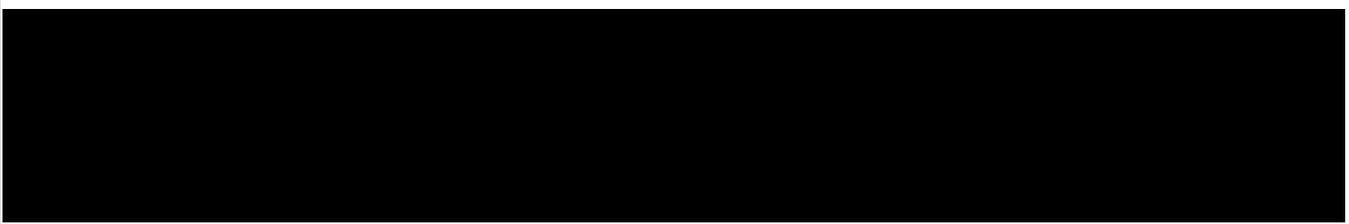
Patient details Sex: -- UNKNOWN -- Pregnant  Age/ date of birth: -- UNKNOWN -- Occupation (if relevant): -- UNKNOWN --

Date of exposure: -- UNKNOWN --

Date of reaction: -- UNKNOWN --

Nature and duration of exposure, reaction details (including symptoms) and outcome:

-- UNKNOWN --



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#### 7. REACTION DATA (continued)



Medical History