ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of 1 vial of 5 ml, 10 ml, 30 ml.
Box of 10 vials of 10 ml.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alizin 30 mg/ml Solution for Injection

2. STATEMENT OF ACTIVE SUBSTANCES

Aglepristone 30 mg/ml

3. PACKAGE SIZE

5 ml
10 ml
30 ml
10 x 10 ml

4. TARGET SPECIES

Dogs (bitches)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP {mm/yyyy}

Shelf life after first opening the immediate packaging: 28 days.
Once broached, use by:

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.

Should any apparent growth or discoloration occur, the veterinary medicinal product should be discarded.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Virbac

14. MARKETING AUTHORISATION NUMBERS

Vm 05653/3011

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial of 5 ml, 10 ml or 30 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alizin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

30 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Alizin 30 mg/ml Solution for Injection for dogs

2. Composition

Each ml contains:

Active substance:
Aglepristone 30 mg

Clear yellow oily solution.

3. Target species

Dogs (bitches).

4. Indications for use

Pregnant bitches: induction of abortion up to 45 days after mating.

5. Contraindications

Do not use in dogs with impaired hepatic or renal function, in diabetic animals or in dogs in poor health.

Do not use in dogs with either manifest or latent hypoadrenocorticism (Addison's disease) or in dogs with a genetic predisposition to hypoadrenocorticism.

Do not use in dogs with known hypersensitivity to aglepristone or the veterinary medicinal product excipient.

6. Special warnings

Special warnings:

Rare cases of lack of efficacy (>0.01 % to < 0.1%) have been reported as part of the pharmacovigilance survey. To reduce the possibility of lack of expected efficacy, avoid the use of Alizin until after the end of oestrus and avoid new mating before the end of oestrus.

In bitches confirmed pregnant, a partial abortion was observed in 5 % of cases in field trials. A thorough clinical examination is always recommended in order to confirm that the uterus content is fully evacuated. Ideally, this examination should be

conducted using ultrasound. This examination should be performed 10 days after treatment and at least 30 days after mating.

In case of partial abortion or no abortion, repeat treatment may be recommended 10 days after treatment, between day 30 and day 45 after mating. Surgery should also be considered.

Special precautions for safe use in the target species:

In the absence of available data, the veterinary medicinal product should be used with caution in dogs with chronic obstructive-airway disease and/or cardiovascular disease, particularly bacterial endocarditis.

Fatalities have been reported subsequent to off-label use in seriously ill bitches with uterine infections. A causal association is difficult to determine but is unlikely.

In up to 50 % of bitches, mating may not be followed by pregnancy. The possibility that a bitch may therefore be treated unnecessarily should be taken into account in evaluating the veterinary medicinal product risk-benefit ratio.

Bitches that remain pregnant despite treatment should be monitored, as viability of the puppies may be compromised.

Possible long-term effects of treatment have not been studied.

Owners should be advised to consult their veterinary surgeon if their dog shows the following signs after treatment with the veterinary medicinal product:
- purulent or haemorragic vaginal discharge
- prolonged vaginal discharge lasting over 3 weeks.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Nor-steroids are used in humans to induce abortion. Accidental injection may be a particular hazard to women who are pregnant, intending to become pregnant or whose pregnancy status is unknown. Care should be taken by the veterinary surgeon when handling the veterinary medicinal product and the person restraining the dog to avoid accidental injection. Pregnant women should administer the veterinary medicinal product with caution. This is an oil-based veterinary medicinal product that may cause prolonged local reactions at the site of injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Women of child-bearing age should avoid contact with the veterinary medicinal product or wear disposable plastic gloves when administering the veterinary medicinal product.

Pregnancy:

Do not administer to pregnant bitches unless it is desirable to terminate the pregnancy.
Do not administer to bitches after the 45th day post mating.

Interaction with other medicinal products and other forms of interaction:

In the absence of available data, a risk of drug interaction between aglepristone and ketoconazole, itraconazole and erythromycin may exist.

As aglepristone is an anti-glucocorticoid, it might reduce the effect of glucocorticoid treatment.

Possible interactions with other medicaments have not been studied.

Overdose:

The administration of 30 mg/kg, i.e. 3 times the recommended dose, in bitches showed no adverse effects, except local inflammatory reactions, related to the larger volumes injected.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Dogs (bitches).

Very common (>1 animal / 10 animals treated):
Injection site inflammation [1], Injection site pain [2, 3] Injection site oedema [3], Injection site thickening [3] Enlarged lymph node (localised) [3] Anorexia, Depression Excitation Diarrhoea
Common (1 to 10 animals / 100 animals treated):
Modified haematological parameters (neutrophilia, neutropenia, thrombocytosis, elevated haematocrit, decreased haematocrit, lymphocytosis, lymphopenia) [4] Modified biochemical parameters (elevated blood urea nitrogen (BUN), elevated creatinine, hyperchloraemia, hyperkalaemia, hypernatremia, elevated alanine aminotransferase (ALT), elevated serum alkaline phosphatase (SAP), elevated aspartate aminotransferase (AST)) [4] Uterine infection, Return to oestrus [5] Vomiting
Rare (1 to 10 animals / 10,000 animals treated):
Hypersensitivity reaction
Very Rare (< 1 animal / 10,000 animals treated, including isolated reports):
Injection site ulcer [3]
Undetermined frequency:
Physiological signs of parturition (foetal expulsion, vaginal discharge, reduced appetite, restlessness and mammary congestion) [6]

[1] At the injection site, size and intensity of the reaction depending on the volume of the veterinary
medicinal product administered.
[2] During and shortly after injection.
[3] All local reactions are reversible and usually disappear within 28 days after injection.

[4] Changes are always transient and reversible.
[5] Early return to oestrus (oestrus interval shortened by 1 to 3 months).
[6] Accompanies abortion in bitches treated after 20 days of gestation.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

8. Dosage for each species, routes and method of administration

Subcutaneous use.

Administer 10 mg per kg of bodyweight of aglepristone, equivalent to 0.33 ml of veterinary medicinal product per kg of bodyweight, twice, 24 hours apart.

Weight of bitch	3 kg	6 kg	9 kg	12 kg	24 kg	30 kg	42 kg
Volume of veterinary medicinal product	1 ml	2 ml	3 ml	4 ml	8 ml	10 ml	14 ml

Following administration of the veterinary medicinal product to dogs, abortion (or resorption) occurs within 7 days.

The stopper can be safely punctured up to 10 times.

9. Advice on correct administration

Severe local reactions can be avoided if the veterinary medicinal product is administered into the scruff of the neck. A light massage of the injection site is recommended.
In large bitches, it is recommended that a maximum of 5 ml is injected at any one site.
This veterinary medicinal product does not contain an antimicrobial preservative. Swab the septum before removing each dose. Use a dry, sterile needle and syringe.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep the vial in the outer carton in order to protect from light.
Should any apparent growth or discoloration occur, the veterinary medicinal product should be discarded.

Do not use this veterinary medicinal product after the expiry date which is stated on the label/carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days.
Keep out of the sight and reach of children.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

- Cardboard box of 1 vial of 5 ml, 10 ml, 30 ml
- Cardboard box of 10 vials of 10 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

February 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

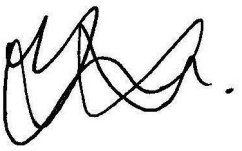
16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

VIRBAC
1ère avenue – 2065 m – L.I.D.
06516 Carros
France

Local representative(s) and contact details to report suspected adverse reactions:

17. Other information



Approved: 10 August 2023