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 AND OTHER SUBSTANCES

Each 1 ml contains:
- active substance
aglepristone……. 30 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

5 ml (, 10 ml or 30 ml)
Box of 10 vials of 10 ml.

5. TARGET SPECIES

Dogs (bitches).

6. INDICATION (S)

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

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use and for user warnings.

10. EXPIRY DATE

Exp. end MM/YY

Shelf life after first opening the immediate packaging: 28 days.
Do not use after the expiry date stated on the label/carton.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused product or waste material should be disposed of in accordance with national requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Virbac – 06516 Carros Cedex - France

16. MARKETING AUTHORISATION NUMBER(S)

Vm 05653/5040

17. MANUFACTURER'S BATCH NUMBER

<Batch> <Lot> <BN> {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alizin 30 mg/ml Solution for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each 1 ml contains:
- active substance
aglepristone .30 mg

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 ml (or 10 ml or 30 ml)

4. ROUTE OF ADMINISTRATION

Subcutaneous administration.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

7. EXPIRY DATE

Exp. end MM/YY
Shelf life after first opening the immediate packaging: 28 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET
Alizin 30 mg/ml Solution for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing-authorisation holder :

Virbac – 1ère avenue – 2065 m - L.I.D. – 06516 Carros Cedex - France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Alizin 30 mg/ml Solution for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each 1 ml contains:
- active substance
aglepristone .30 mg

4. INDICATIONS

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

5. CONTRA-INDICATIONS

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 product excipient.

6. ADVERSE REACTIONS

In bitches treated after 20 days of gestation, abortion is accompanied by the physiological signs of parturition: fetal expulsion, vaginal discharge, reduced appetite, restlessness and mammary congestion. In field trials, 3.4 % of dogs suffered from uterine infections. After induced abortion with the veterinary medicinal product, an early return to oestrus is frequently observed (oestrus - oestrus interval shortened by 1 to 3 months).

Side effects such as anorexia (25 %), excitation (23 %), depression (21 %), vomiting (2 %) and diarrhoea (13 %) have been reported from field trials.

In field trials, the administration of the veterinary medicinal product produced pain during and shortly after injection in 17 % of dogs and a local inflammatory reaction at the injection site in 23 % of dogs. The size and intensity of this reaction depended on the volume of the veterinary medicinal product which was administered. Oedema, skin thickening, local lymph-node enlargement and ulceration may occur. All local reactions are reversible and will usually disappear within 28 days after injection.
In field trials, administration of the veterinary medicinal product induced haematological/biochemical changes in 4.5 % of dogs. These changes were always transient and reversible. The modified haematological parameters were as follows: neutrophilia, neutropaenia, thrombocytosis, haematocrit variation, lymphocytosis, lymphopaenia.
The modified (elevated) biochemical parameters were as follows: urea, creatinine, chloride, potassium, sodium, ALT, ALP, AST.
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.
In rare cases (frequency > 1/10000 and < 1/1000), a hypersensitivity reaction has been/can be observed.

7. TARGET SPECIES

Dogs (bitches).

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

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 product	1 ml	2 ml	3 ml	4 ml	8 ml	10 ml	14 ml

Inject subcutaneously (only).
Following administration of the product to dogs, abortion (or resorption) occurs within 7 days.

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 PERIOD

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 product should be discarded.
Do not use after the expiry date stated on the label/carton.
Shelf life after first opening the immediate packaging: 28 days.
Keep out of reach and sight of children.

12. 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.

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 product risk-benefit ratio.

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.

Do not mix with other veterinary medical products.

User warnings

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 product and the person restraining the dog to avoid accidental injection. Pregnant women should administer the product with caution. This is an oil-based product that may cause prolonged local reactions at the site of injection. In case of accidental injection, seek urgent medical advice and show the doctor this warning.

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

Do not administer to pregnant bitches unless it is desirable to terminate the pregnancy.

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.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused product or waste material should be disposed of in accordance with national requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing-authorisation holder.

Approved : 10 August 2023