PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trilocur 50 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

For each ml:
Active substance: Trilostane 50 mg

3. PACKAGE SIZE

10 ml
25 ml
36 ml
50 ml
72 ml
100 ml
1 ml and 5 ml oral syringe

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral Suspension.

7. WITHDRAWAL PERIODS

Not applicable.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

User warning: This product may decrease testosterone synthesis and has anti-progesterone properties. Women who are pregnant or are intending to become pregnant should not handle this product.

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

Emdoka

14. MARKETING AUTHORISATION NUMBERS

Vm 34534/5006

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {vial label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trilocur 50 mg/ml oral suspension

2. STATEMENT OF ACTIVE SUBSTANCES

For each ml :
Active substance : Trilostane 50 mg

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Oral suspension.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Not applicable.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Emdoka

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {vial label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trilocur

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Active substance : Trilostane 50 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Trilocur 50 mg/ml oral suspension for dogs

2. Composition

Active substance: Trilostane 50 mg/ml

3. Target species

Dogs

4. Indications for use

For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome) in dogs.

5. Contraindications

Do not use in animals suffering from primary hepatic disease and/or renal insufficiency.
Do not use where there is suspected hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:
An accurate diagnosis of hyperadrenocorticism is essential.
Where there is no apparent response to treatment, the diagnosis should be re-evaluated. Dose increases may be necessary.
Veterinarians should be aware that dogs with hyperadrenocorticism are at increased risk of pancreatitis. This risk may not diminish following treatment with trilostane.

Special precautions for safe use in the target species:
As the majority of cases of hyperadrenocorticism are diagnosed in dogs between the ages of 10-15 years, other pathological processes are frequently present. It is particularly important to screen cases for primary hepatic disease and renal insufficiency as the product is contraindicated in these cases.

Subsequent close monitoring during treatment should be carried out. Particular attention should be paid to liver enzymes, electrolytes, urea and creatinine.

The presence of diabetes mellitus and hyperadrenocorticism together requires specific monitoring.

If a dog has previously been treated with mitotane, its adrenal function will have been reduced. Experience in the field suggests that an interval of at least a month should elapse between cessation of mitotane and the introduction of trilostane. Close monitoring of adrenal function is advised, as dogs may be more susceptible to the effects of trilostane.

The veterinary medicinal product should be used with extreme caution in dogs with pre-existing anaemias as further reductions in packed-cell volume and haemoglobin may occur. Regular monitoring should be undertaken.

The veterinary medicinal product contains the excipient xylitol which may be a cause of adverse effects if administered at high doses. Administration of Trilocur 50 mg/ml oral suspension for dogs at doses in excess of 10 mg trilostane/kg bodyweight has the potential to result in xylitol toxicity. In dogs requiring doses higher than 10 mg trilostane/kg, use an alternative trilostane product.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Trilostane may decrease testosterone synthesis and has anti-progesterone properties. Women who are pregnant or are intending to become pregnant should not handle this product.
The content of the product may cause skin and eye irritation and sensitisation. Take care to avoid accidental contact with the skin and eyes. In case of accidental skin contact, wash the affected area with soap and water. In case of accidental contact with the eyes, immediately rinse with plenty of water.
If skin or eye irritation persists, seek medical advice.
People with known hypersensitivity to trilostane, vanillin, or sodium benzoate should avoid contact with the veterinary medicinal product.
Accidental ingestion may cause harmful effects, including nausea, vomiting, and diarrhoea. Care should be taken to avoid accidental ingestion, especially by a child. Keep filled syringes away from children and store used syringes out of the sight and reach of children. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Wash hands with soap and water after use.

Pregnancy and lactation:
Do not use in pregnant or lactating bitches.

Fertility:
Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:
The possibility of interactions with other medicinal products has not been specifically studied. Given that hyperadrenocorticism tends to occur in older dogs, many will be receiving concurrent medication. In clinical studies, no interactions were observed. The risk of hyperkalaemia developing should be considered if trilostane is used in conjunction with potassium-sparing diuretics or angiotensin converting enzyme inhibitors (ACE inhibitors). The concurrent use of such drugs should be subject to a risk-benefit analysis by the veterinary surgeon, as there have been a few reports of

deaths (including sudden death) in dogs when treated concurrently with trilostane and an ACE inhibitor.

Overdose:
Overdose may lead to signs of hypoadrenocorticism (lethargy, anorexia, vomiting, diarrhoea, cardiovascular signs, collapse). There were no mortalities following chronic administration at 36 mg/kg to healthy dogs, however mortalities may be expected if higher doses are administered to dogs with hyperadrenocorticism. There is no specific antidote for trilostane. Treatment should be withdrawn and supportive therapy, including corticosteroids, correction of electrolyte imbalances and fluid therapy may be indicated depending on clinical signs.
In cases of acute overdosage, induction of emesis followed by administration of activated charcoal may be beneficial. Any iatrogenic adrenocortical insufficiency is usually quickly reversed following cessation of treatment. However in a small percentage of dogs, effects may be prolonged. Following a one week withdrawal of trilostane treatment, treatment should be reinstated at a reduced dose rate.

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:

Uncommon (1 to 10 animals / 1,000 animals treated):	Lethargy[2], anorexia[2], vomiting[2], diarrhoea[2]
Rare (1 to 10 animals / 10,000 animals treated):	hypoadrenocorticism, hypersalivation. Bloated, ataxia, muscle tremor, skin disorders, renal insufficiency[3] and arthritis[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Weakness[2], adrenal necrosis[1] and sudden death
Undetermined frequency (Cannot be estimated from the available data):	Acute Addisonian crisis (collapse)

1 May result in hypoadrenocorticism.
2 These signs associated with iatrogenic hypoadrenocorticism may occur, particularly if monitoring is not adequate (see section 8). Signs are generally reversible within a variable period following withdrawal of treatment.
Lethargy, vomiting, diarrhoea and anorexia have been seen in dogs treated with trilostane in the absence of evidence of hypoadrenocorticism.
3 May be unmasked by treatment with the product.
Treatment may unmask arthritis due to a reduction in endogenous corticosteroid levels.

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 at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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

Administer orally, once daily with food.
The starting dose for treatment is approximately 2 mg/kg. Titrate the dose according to individual response as determined by monitoring (see below). If a dose increase is required, slowly increase the once daily dose. Administer the lowest dose necessary to control the clinical signs.
Ultimately, if symptoms are not adequately controlled for an entire 24 hour inter-dose period, consider increasing the total daily dose by up to 50% and dividing it equally between morning and evening doses.
A small number of animals may require doses significantly in excess of 10 mg per kg body weight per day, in these cases an alternative trilostane product should be used (see section 6 Special warnings). In these situations appropriate additional monitoring should be implemented.
The dose can be calculated as follows:

$$Volume\ (ml) = \frac{\text{Daily dose } \left(\frac{\text{mg}}{\text{kg}}\right) \text{x body weight (kg)}}{10\ \left(\frac{\text{mg}}{\text{ml}}\right)}$$

Monitoring:
Samples should be taken for biochemistry (including electrolytes) and an ACTH stimulation test pre-treatment and then at 10 days, 4 weeks, 12 weeks, and thereafter every 3 months, following initial diagnosis and after each dose adjustment. It is imperative that ACTH stimulation tests are performed 4– 6 hours post-dosing to enable accurate interpretation of results. Dosing in the morning is preferable as this will allow your veterinary surgeon to perform monitoring tests 4-6 hours following administration of the dose. Regular assessment of the clinical progress of the disease should also be made at each of the above time points.
In the event of a non-stimulatory ACTH stimulation test during monitoring, treatment should be stopped for 7 days and then re-started at a lower dose. Repeat the ACTH stimulation test after a further 14 days. If the result is still non-stimulatory, stop treatment until clinical signs of hyperadrenocorticism recur. Repeat the ACTH stimulation test one month after re-starting treatment.

Shake well before use.

9. Advice on correct administration

10. Withdrawal periods

11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze

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: 6 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
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

POM-V ('Veterinary medicinal product subject to prescription')

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 34534/5006

Pack sizes:
Cardboard box containing one bottle of 10 ml, and a 1-ml and a 5-ml polypropylene measuring
syringe
Cardboard box containing one bottle of 25 ml, and a 1-ml and a 5-ml polypropylene measuring
syringe
Cardboard box containing one bottle of 36 ml, and a 1-ml and a 5-ml polypropylene measuring
syringe
Cardboard box containing one bottle of 50 ml, and a 1-ml and a 5-ml polypropylene measuring
syringe
Cardboard box containing one bottle of 72 ml, and a 1-ml and a 5-ml polypropylene measuring
syringe
Cardboard box containing one bottle of 100 ml, and a 1-ml and a 5-ml polypropylene measuring
syringe
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Emdoka
John Lijsenstraat 16
2321 Hoogstraten
Belgium

Manufacturer responsible for batch release:
Lelypharma bv
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

Local representative and contact details to report suspected adverse reactions:
DUGV (UK) Ltd.
Union House
111 New Union Street
Coventry, CV1 2NT

17. Other information

POM-V

Gavin Hall

Approved: 21 August 2024