PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Bottle label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tardak™ 10 mg/ml Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

-

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

For use in male dogs and cats.

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramuscular or subcutaneous injection.

For full details of use, dosage, contra-indications & warnings, see package leaflet.

8. WITHDRAWAL PERIOD

-

9. SPECIAL WARNING(S), IF NECESSARY

Shake container before use.

10. EXPIRY DATE

Exp. date:

11. SPECIAL STORAGE CONDITIONS

Protect from light. Do not store above 25°C.

Following withdrawal of the first dose use the product within 28 days. Discard unused material.

Keep container in the outer carton.

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

-

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4149

17. MANUFACTURER'S BATCH NUMBER

Batch No:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Folding carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tardak™ 10 mg/ml Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 10 mg/ml delmadinone acetate.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

For use in male dogs and cats.

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer by intramuscular or subcutaneous injection.

For full details of use, dosage, contra-indications & warnings, see package leaflet.

8. WITHDRAWAL PERIOD

-

9. SPECIAL WARNING(S), IF NECESSARY

Shake container before use.

10. EXPIRY DATE

Exp. Date:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

Following withdrawal of the first dose use the product within 28 days. Discard unused material.

Once broached, use by:

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

-

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4149

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

PACKAGE LEAFLET FOR: Tardak™ 10 mg/ml Suspension 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:

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:

Bela-Pharm GmbH & Co
Lohner Str. 19
Vechta
49377
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tardak™ 10 mg/ml Suspension for Injection

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

Tardak 10 mg/ml Suspension for Injection is a sterile, aqueous suspension of micronized delmadinone acetate, containing 10 mg/ml.

Also contains 0.2 mg/ml benzalkonium chloride and 1.0 mg/ml EDTA as preservatives.

4. INDICATIONS

The veterinary medicinal product is for use in male dogs and cats in the following indications:

1. The treatment of hypersexuality (excessive or aberrant sexual behaviour, including vagrancy) not related to sociopathic disorders.
2. The relief of prostatic hypertrophy whether benign, carcinomatous or when due to chronic inflammatory processes. (In cases of the latter, relief cannot be expected unless appropriate accompanying therapy such as corticosteroids or antibiotics is also instituted).
3. For the treatment of circum-anal tumours.

4. For the treatment of certain forms of aggressiveness, nervousness, epileptiform seizures and corticosteroid resistant pruritus (developing into dermatoses and accompanied by alopecia).

5. CONTRAINDICATIONS

Do not use in patients with diabetes mellitus, severe impairment of liver and kidney function or mammary tumours.

Do not use in patients receiving long term treatment with glucocorticoids or in dogs already receiving progestogens.

Do not use in male dogs under one year.

Not for intravenous administration.

6. ADVERSE REACTIONS

Transient side-effects of increased appetite, polydipsia and polyuria have occasionally been seen. Controlling food intake will prevent an increase in bodyweight. However, where these effects are excessive, therapy should cease.

Breeding animals treated with the product may show reduced fertility and reduced libido. The time to return of normal reproductive function is unpredictable.

As some progestogen injections can cause local changes in the hair coat such as lightening of colour and/or hair loss, it is recommended that subcutaneous injections are given at an inconspicuous site e.g. inner surface of the thigh.

Manifestation of latent diabetes mellitus, elevated plasma liver enzymes (ALT, alkaline phosphate), changes in teats (tumours, hyperplasia, cysts, galactorrhoea) may occur.

In rare cases, transient digestive disorders have been reported.

Delmadinone acetate may cause adrenal suppression. In stress situations, the treated animal is then at risk of developing adrenocortical insufficiency during or after treatment.

7. TARGET SPECIES

Dogs and cats.

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

Route: intramuscular or subcutaneous injection. Dose levels should be individually selected, taking into consideration the weight of the animal and the severity of the condition to be treated. Shake the vial before use to ensure a homogeneous suspension.

The following dosage recommendations may be taken as a guideline:

Bodyweight	Recommended dosage	
	Dose of active substance (mg/kg)	Dose volume of product (ml/kg)
Up to 10 kg	1.5 – 2.0	0.15 – 0.20
10 to 20 kg	1.0 – 1.5	0.10 – 0.15
20 kg and above	1.0	0.10

In most cases it is necessary to allow 2 to 4 days to elapse before the effect of the treatment is observed. Animals not showing improvement within 8 days should be treated a second time with at least the dose level previously used. Do not exceed the maximum recommended dose.

Animals showing a favourable response can be expected to require follow-up treatment after a 3 to 4 week period. Further treatment for “social indications” is recommended at the first sign of reappearance of the effectively controlled indication.

9. ADVICE ON CORRECT ADMINISTRATION

None

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Shake the container before use.

Do not store above 25°C. Protect from light.

Keep container in outer carton.

Following withdrawal of the first dose, use the product within 28 days. Discard any unused material.

When the container is broached for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining should be discarded should be worked out. This discard date should be written in the space provided on the carton.

Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Owners should be clearly warned that an immediate effect cannot be expected following administration of the veterinary medicinal product. In most cases it is necessary to allow two to four days to elapse before the effect of treatment is observed.

When the product is used to treat hypersexuality the effects on androgen-related sexual behaviour in dogs are variable and therefore treatment failure should be anticipated in some cases.

Special warnings for use in animals:

The veterinary medicinal product should not be administered to diabetic animals.

Fertility:

Studies to investigate the return of fertility in breeding male dogs and cats have not been carried out. Breeding animals treated with the product may show reduced fertility (suppression of spermatogenesis) and reduced libido. The time to return of normal reproductive function is unpredictable.

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

Preparations containing progestogens should be handled with care, particularly by women of childbearing age.
Avoid contact with skin. Impervious gloves should be worn whilst administering this product.
In case of contact with skin, wash off any product with soap and water.
If eye exposure occurs, flush immediately with water. In case of accidental injection, seek medical advice immediately and show the package leaflet or the label to the physician.
For animal treatment only.

Interaction with other medicinal products and other forms of interaction:

This product should be used with great care when animals are under treatment with other steroids.

The effect of progestogenic substances may be reduced by concomitant administration of enzyme inducers such as carbamazepine, phenobarbital or rifampicin.

Delmadinone acetate reduces sensitivity to insulin.

Overdose (symptoms, emergency procedures, antidotes):

No specific treatment is indicated.

Incompatibilities:

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

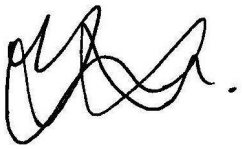
15. OTHER INFORMATION

Package quantities: 10 ml vials.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4149



Approved: 27 August 2020