# A. LABELLING

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

**Outer carton**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tardastrex 10 mg/ml Suspension for Injection for Dogs and Cats[UK]
Tardak 10 mg/ml Suspension for Injection for Dogs and Cats [CZ, HR, HU, PL, SI, SK]
delmadinone acetate

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contents per ml:

**Active substances**
Delmadinone Acetate 10.0 mg

## 3. PHARMACEUTICAL FORM

Suspension for injection

## 4. PACKAGE SIZE

10 ml

## 5. TARGET SPECIES

Dogs and cats

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or subcutaneous use.
Shake the vial before use.
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

## 9. SPECIAL WARNING(S), IF NECESSARY

The veterinary medicinal product should not be used in dogs already receiving progestogens.
Read the package leaflet before use.

## 10. EXPIRY DATE

EXP {month/year}> MMM/YY
Once broached use by ……..
Shelf life after first broaching container: 28 days

## 11. SPECIAL STORAGE CONDITIONS

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

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

For animal treatment only.

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

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4191

## 17. MANUFACTURER'S BATCH NUMBER

Lot {number}:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**Glass bottle containing 10 ml**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tardastrex 10 mg/ml Suspension for Injection for Dogs and Cats [UK]
Tardak 10 mg/ml Suspension for Injection for Dogs and Cats [CZ, HR, HU, PL, SI, SK]
delmadinone acetate

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contents per ml:
Delmadinone Acetate 10.0 mg

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

10 ml

## 4. ROUTE(S) OF ADMINISTRATION

For intramuscular or subcutaneous use.

## 5. WITHDRAWAL PERIOD

## 6. BATCH NUMBER

Lot {number}:

## 7. EXPIRY DATE

EXP {month/year}
Once broached use by ……..
Shelf life after first broaching container: 28 days

## 8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 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
5th Floor, 6 St. Andrew Street
London
EC4A 3AE

**Manufacturer responsible for batch release:**
Bela-pharm GmbH & Co.,
Lohner Str. 19,
VECHTA
Germany-49377

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tardastrex 10 mg/ml Suspension for Injection for Dogs and Cats [UK]
Tardak 10 mg/ml Suspension for Injection for Dogs and Cats [CZ, HR, HU, PL, SI, SK]
delmadinone acetate

## 3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each ml contains:

**Active substances**

| | |
|---|---|
| Delmadinone Acetate | 10.0 mg |

**Preservatives**

| | |
|---|---|
| Benzalkonium Chloride | 0.2 mg |
| Disodium edetate | 1.0 mg |

White suspension.

## 4. INDICATION(S)

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 behavior, 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, mammary tumors.
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

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.
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.
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 phosphatase), changes in teats (tumors, 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.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs and cats

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

Route: Intramuscular or subcutaneous use. 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 two to four days to elapse before the effect of the treatment is observed. Dogs not showing improvement within eight days should be treated a second time with at least the dose level previously given. Do not exceed the maximum recommended dose.

Animals showing a favourable response can be expected to require follow-up treatment after a three to four week period. Further treatment in "social indications" (eg. aggressiveness, nervousness) is recommended at the first sign of re-appearance of the effectively controlled indication.

## 9. ADVICE ON CORRECT ADMINISTRATION

None

## 10. WITHDRAWAL PERIOD

Not applicable

## 11. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton in order to protect from light.
Following withdrawal of the first dose, use the product within 28 days. Discard any unused material.
Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

## 12. SPECIAL WARNINGS

**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.

**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.

**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.

**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 MATERIAL, 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

## 15. OTHER INFORMATION

Pack sizes:
Carton containing 10 ml vial.

Approved: 19 April 2016