SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tardak 10 mg/ml Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredient	mg/ml
Delmadinone Acetate	10.0
Excipients	
Benzalkonium Chloride (preservative)	0.2
EDTA	1.0

For a full list of excipients, see Section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
White suspension

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats.

4.2 Indications for use, specifying the target species

The product is for use in male dogs and cats in the following indications:
The treatment of hypersexuality (excessive or aberrant sexual behaviour, including vagrancy) not related to sociopathic disorders.
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).
For the treatment of circum-anal tumours.
For the treatment of certain forms of aggressiveness, nervousness, epileptiform seizures and corticosteroid-resistant pruritus (developing into dermatoses and accompanied by alopecia).

4.3 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.

4.4 Special warnings for each target species

Owners should be clearly warned that an immediate effect cannot be expected following administration of the 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.
See Section 4.9.

4.5 Special precautions for use

i. Special precautions for use in animals

Progestogens should not be administered to diabetic animals.

ii. 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.

4.6 Adverse reactions (frequency and seriousness)

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 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.

4.7 Use during pregnancy, lactation or lay

Studies to investigate the return of fertility in breeding male dogs and cats have not been carried out. See also section 4.6.

4.8 Interaction with other medicinal products and other forms of interaction

This product should be handled with great care when animals are treated by other steroid compounds.
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.

4.9 Amounts to be administered and 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.

Recommended dosage:

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” (e.g. aggressiveness, nervousness) is recommended at the first sign of re-appearance of the effectively controlled indication.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No specific treatment is indicated. See also section 4.6.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Sex hormones and modulators of the genital system, other progestogens. Delmadinone.

ATC Vet Code: QG03DX91

5.1 Pharmacodynamic properties

Delmadinone acetate is a synthetic long-acting progesterone derivative with a progestogenic, anti-androgenic and weak glucocorticoid action. Delmadinone acetate blocks androgen receptors, inhibits 5 -reductase, which catalyses the transformation of testosterone to the more potent androgen 5-dihydrotestosterone, and decreases the production of testosterone by inhibiting gonadotropin release. As a result, it can have a beneficial effect on androgen-related diseases such as prostate hypertrophy and perianal gland adenomas. The effects on androgen-related undesirable sexual behaviour in dogs are variable, so treatment failure should be anticipated in a proportion of treated dogs.

5.2 Pharmacokinetic particulars

No pharmacokinetic studies have been conducted in dogs and cats. However, the clinical efficacy of the product confirms that the drug is bioavailable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
EDTA
Polyethylene glycol 4000
Citric acid monohydrate
Sodium citrate dehydrate
Polysorbate 80
Sodium chloride
Hydrochloric acid (pH adjustment)
Sodium hydroxide (pH adjustment)
Water for injections

6.2 Incompatibilities

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

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate container: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.
Shake container before use.
Following withdrawal of the first dose, use the product within 28 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

Carton containing 10 ml colourless glass vial with a blue halobutyl (siliconised) rubber bung and aluminium overseal.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

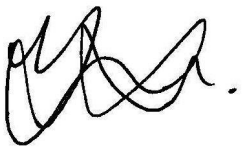
Vm 42058/4149

9. DATE OF THE FIRST AUTHORISATION

23 April 1992

10. DATE OF REVISION OF THE TEXT

August 2020



Approved: 27 August 2020