

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10996/016/001**
Case No: 7004741

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Intervet Ireland Limited

Magna Drive, Magna Business Park, Dublin 24, Ireland

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Durateston Solution for Injection

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation,unless revoked, shall continue in force from **30/07/2008**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Durateston solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances

Testosterone propionate	6 mg
Testosterone phenylpropionate	12 mg
Testosterone isocaproate	12 mg
Testosterone decanoate	20 mg

Excipients

Benzyl alcohol (as preservative)	104 mg
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For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection

Light yellow, sterile, oily solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats

4.2 Indications for use, specifying the target species

To provide androgenic therapy over a period of 4 weeks after a single administration

Androgen therapy has been found to be effective for the following specific indications:

- treatment of deficient sex drive in male animals of all species
- treatment of cryptorchidism prior to castration in male dogs
- reversion of feminisation in male dogs (e.g. due to Sertoli cell tumours)
- treatment of oestrogen dependent mammary tumours in the bitch
- suppression of oestrus in the bitch (particularly in racing greyhounds in which progestagen treatment can reduce performance)
- treatment of certain skin condition in the dog and cat (e.g feline endocrine alopecia, due to hypogonadism in male dogs and cats, senile alopecia in male dogs).
- supportive anabolic therapy (e.g. in cases of debility, senile decline, etc) in dogs and cats.

4.3 Contraindications

Durateston should not be given to animals with cardiac insufficiency or a prior history of liver or kidney disease, as medication may be associated with sodium and water retention.

Durateston should not be used in pregnant animals since female puppies may develop urinogenital abnormalities in utero.

Durateston should not be administered to dogs with prostate hypertrophy or with androgen dependent neoplastic conditions.

Not to be used in known cases of hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

This product contains benzyl alcohol, which has been documented to cause adverse reactions in neonates. For this reason, the product should not be used in very young animals.

4.5 Special precautions for use

Special precautions for use in animals

None

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

Do not dilute with other compounds.

4.6 Adverse reactions (frequency and seriousness)

Undesirable virilisation such as clitoral enlargement and a low grade vaginitis can occur from overdosage in certain individuals.

The administration of androgens to prepubertal animals may result in early epiphyseal closure. Use of Durateston in male cats may cause spraying of urine.

4.7 Use during pregnancy, lactation or lay

Durateston should not be used in pregnant animals since female puppies may develop urinogenital abnormalities in utero.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Dog and cat 0.5 - 1.0 ml/10 kg

As with all physiological hormone therapies, there can be considerable variation in response to treatment; the above dosages may need to be adjusted according to clinical response, but should not exceed 2 ml/10 kg. Administer by subcutaneous or intramuscular injection, observing usual aseptic precautions.

For sustained androgen therapy, treatment should be repeated every 28 days.

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

May lead to virilisation; no treatment or antidote recommended.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Androgens

ATCvet code: QG03BA03

5.1 Pharmacodynamic properties

Testosterone is the naturally occurring androgenic hormone. The basic effects of testosterone can be summarised as follows:

- stimulation of the development of the secondary male sexual characteristics (anatomical and behavioural)
- anti-oestrogenic activity
- negative feedback activity on gonadotrophin release from the pituitary gland

The esters of testosterone, which are the active constituents of Durateston must be hydrolysed to testosterone (which is then distributed, metabolised and excreted in exactly the same manner as the endogenous compound) before becoming bioavailable.

The range of esters chosen have decreasing susceptibilities to hydrolysis and thus act in sequence, hence the duration of action of the product is approximately 28 days after injection.

5.2 Pharmacokinetic properties

The esters of testosterone, which are the active constituents of Durateston must be hydrolysed to testosterone (which is then distributed, metabolised and excreted in exactly the same manner as the endogenous compound) before becoming bioavailable. The range of esters chosen have decreasing susceptibilities to hydrolysis and thus act in sequence, hence the duration of action of the product is approximately 28 days after injection.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol

Arachis oil

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

Shelf-life after withdrawal of the first dose: 28 days.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light. At low temperatures the product may become viscous. Warming the vial in the hand will return the contents to the normal state.

6.5 Nature and composition of immediate packaging

Glass, Type I (Ph.Eur) 5 ml vials, with a halogenated butylrubber stopper closed with a colourcoded aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

INTERVET IRELAND Ltd.
Magna Drive
Magna Business Park
Citywest Road
DUBLIN 24

8 MARKETING AUTHORISATION NUMBER(S)

10996/16/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT

30th July 2008