IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10996/002/002**
Case No: 7003255

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:

Laurabolin 50 mg/ml 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 previously revoked, shall continue in force from **30/09/2007**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, 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

Laurabolin 50 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active Substance	
Nandrolone laurate	50 mg
Excipient	
Benzyl alcohol	104 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Light yellow solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and Cats.

4.2 Indications for use, specifying the target species

Nandrolone is a potent anabolic steroid with negligible androgenic or progestogenic activity, for use in small animals.

Laurabolin, which gives anabolic activity for 3-4 weeks following a single injection, is indicated for use in dogs and cats to treat conditions in which anabolic therapy is considered to be beneficial, e.g. chronic renal failure, debility, weight loss and inappetance in ageing animals, cachexia, conditions in which healing is delayed e.g. non-union of bone fractures, supportive therapy in orthopaedic conditions and to counter the catabolic effects of prolonged corticosteroid therapy.

4.3 Contraindications

Laurabolin should not be given to pregnant animals.

Do not use in known cases of hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

As with all oily solutions, injection site reactions may occur.

This product contains benzyl alcohol, which has been documented to cause adverse reactions in neonates. For this reason, Laurabolin 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

None.

4.6 Adverse reactions (frequency and seriousness)

None, other than those noted under “Overdose”.

4.7 Use during pregnancy, lactation or lay

Laurabolin is contra-indicated in pregnant animals.

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, 2-5 mg/kg, by subcutaneous or intramuscular injection, observing normal aseptic precautions.
For sustained anabolic therapy, treatment should be repeated every 3-4 weeks.
As with all hormone therapy, there can be considerable variation in response to treatment. The dose should be adjusted according to clinical response.
Avoid the introduction of contamination during use.

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

Unduly prolonged dosage, or overdosage, may cause signs of androgenic activity to appear, especially in entire female animals.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anabolic steroids

ATCvet Code: QA14AB01

5.1 Pharmacodynamic properties

Nandrolone is a testosterone derivative which has very marked anabolic and anti-catabolic action whilst in the recommended therapeutic dosage it has negligible androgenic or progestagenic activity. It may therefore be used in both male and female with equally safe and potent activity. Positive effects on nitrogen, calcium and phosphorus metabolism are promoted, together with normalisation of tissue water/electrolyte balance.

Laurabolin is indicated whenever excessive tissue breakdown or extensive repair processes are proceeding, particularly in convalescence, geriatrics, tendon and bone damage and after surgery. The effects of each treatment last approximately three weeks.
After release from the intramuscular or subcutaneous depot, it has been shown that the nandrolone ester enters the peripheral circulation and is immediately hydrolysed, releasing the active substance, nandrolone. The laurate ester of nandrolone has been compared with the phenylpropionate or decanoate esters. The T1/2 for the intra-muscular depot of nandrolone laurate in the rat is 243 hours compared with 130 hours for the decanoate, 25 hours for the phenylpropionate and 0.6 hours for nandrolone. This reflects the duration of action of the esters - 1 week for the phenylpropionate, 2-3 weeks for the decanoate and 3-4 weeks for the laurate.

5.2 Pharmacokinetic properties

Excretion and metabolic studies were carried out with nandrolone in rats. 3H nandrolone and/or its metabolites were not retained or stored in the body of rats. The biological half life of the radioactivity was 1-2 days. A pharmacokinetic study was performed in dogs. The nandrolone levels rose slowly after injection, reaching peak levels after an average of 5 days. Thereafter levels decreased steadily with an elimination half life of approximately 12 days. Twenty-one days after the injections, measurable levels of nandrolone were still present. There were no differences in pharmacokinetics between male and female animals. It should be noted that the dose of Laurabolin administered (1 mg/kg) was less than the range recommended in the data sheet/package insert: 2-5 mg/kg. The plasma levels after treatment would thus have a somewhat higher peak and slightly longer duration of action.

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 first broaching the vial: 28 days.

6.4 Special precautions for storage

Do not store above 25^{o}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

Hydrolytic Type I glass vial with rubber stopper, closed with a colour coded aluminium cap. Each vial contains 10 ml solution.

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)

VPA 10996/2/2

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2007

10 DATE OF REVISION OF THE TEXT