# Summary of Product Characteristics

## 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Laurabolin 25 mg/ml solution for injection

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains

| | | |
|---|---|---|
| Active substance | | |
| Nandrolone laurate | 25 | mg |
| Excipients | | |
| Benzyl alcohol (E1516) | 104 | mg |

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Solution for injection.
Light yellow oily solution.

## 4 CLINICAL PARTICULARS

### 4.1 Target Species

Dogs and cats.

### 4.2 Indications for use, specifying the target species

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 inappetence 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

Do not use in pregnant animals.
Do not use in animals with hypercalcaemia.
Do not use in animals with androgenic dependent tumours.
Do not use in known cases of hypersensitivity to the active substance or any of the excipients.

### 4.4 Special warnings for each target species

None.

### 4.5 Special precautions for use

Special precautions for use in animals
Prolonged administration may cause signs of the androgenic activity to appear, especially in entire female animals.
The product contains benzyl alcohol, which has been documented to cause adverse reactions in neonates. For this reason, do not use in very young animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
In the event of accidental self-injection, transient painful, local reactions may occur. Avoid accidental self-injection. In the case of accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.

This product contains benzyl alcohol and can cause skin irritation. Avoid contact with skin. In the case of contact with skin, wash with soap and water. If irritation persists, seek medical advice. Wash hands after use.
The product can cause eye irritation. Avoid contact with eyes. If the product comes into contact with the eyes, rinse the eyes immediately with plenty of water and seek medical attention if irritation persists.
Virilisation of the foetus may occur if pregnant women are exposed to the product. Therefore, the veterinary medicinal product should not be administered by pregnant women or women trying to conceive.
People with known hypersensitivity to nandrolone or any of the excipients should avoid contact with the veterinary medicinal product.

**4.6 Adverse reactions (frequency and seriousness)**

Long-term use can lead to a change in behavior in very rare cases. This is reversible after stopping treatment.
Androgenic side effects can be observed in animals treated with the veterinary medicinal product, in particularly in female animals, in very rare cases.
The frequency of adverse reactions is defined using the following convention:
-very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
-common (more than 1 but less than 10 animals in 100 animals)
-uncommon (more than 1 but less than 10 animals in 1,000 animals)
-rare (more than 1 but less than 10 animals in 10,000 animals)
-very rare (less than 1 animal in 10,000 animals, including isolated reports).

**4.7 Use during pregnancy, lactation or lay**

Do not use in pregnant animals.

**4.8 Interaction with other medicinal products and other forms of interactions**

There is no information on the concurrent use with anticoagulants in dogs.
In humans anabolic steroids may potentiate the effects of anticoagulants.
Steroids are known to alter insulin sensitivity. Diabetic animals should be monitored carefully and insulin dose adjustment might be necessary.

**4.9 Amounts to be administered and administration route**

Dose: 2 – 5 mg/kg.
Route of administration: Subcutaneous or intramuscular injection.

As with all hormone therapy, there can be considerable variation in response to treatment. The dose should be adjusted according to clinical response.
For sustained anabolic therapy, treatment should be repeated every 3 – 4 weeks.

Swab stopper before removing each dose. Avoid the introduction of contamination during use.
Observe normal aseptic precautions.

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

Overdose 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; Estren derivatives; nandrolone
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 ongoing, particularly during convalescence, in geriatrics, in case of 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 t½ 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 particulars**

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 (E1519)
Arachis oil

**6.2 Major 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 packaging: 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**

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 derived from the use of such products**

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 Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA10996/002/001

**9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 01 October 1987
Date of last renewal: 30 September 2007

**10 DATE OF REVISION OF THE TEXT**

February 2021