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 contain
active substance:

Nandrolone laurate	25 mg
equivalent to nandrolone	15 mg

Other substance:
Benzyl alcohol 10.4% w/v

For 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

Nandrolone is a testosterone derivative which can be used in the supportive management of chronic renal failure.

4.3 Contra-indications

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

4.4 Special warning for each target species

To be used with caution in known cases of hepatic impairment.

4.5 Special precautions for use

i) Special precautions for use in animals

None.

ii) Special precautions to be taken by the person administering the medicinal product to the 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 particular 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 or lactation

Laurabolin is contra-indicated in pregnant animals

4.8 Interaction with other medicinal products and other forms of interaction

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

Species	*Dosage*
Dog	2-5 mg/kg
Cat	2-5 mg/kg

As with all hormone therapy there can be considerable variation in response to treatment; the above dosages may need to be adjusted according to clinical response. Treatment may be repeated every 21 days.

Administer by subcutaneous or intramuscular injection, observing usual aseptic precautions.
Swab the septum before removing each dose. Use a dry sterile needle and syringe and avoid introduction of contamination.

Further information:
The product may be used to continue treatment initiated with similarly acting oral preparations. Such preparations may also be used to continue therapy commenced with this product to allow more rapid termination of treatment if necessary.

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

No specific treatment or antidote recommended.

4.11 Withdrawal period

Not applicable

5. PHARMACOLOGICAL PROPERTIES

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, new born animals, geriatrics, tendon and bone damage and after surgery. The effects of each treatment last approximately three weeks.

ATC Vet Code: QA14AB01

5.2 Pharmacokinetic particulars

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.

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 Major incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 36 months.
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 temperature the product may become viscous. Warming the product in the hand will return the contents to the normal state.
Keep the container in the outer carton.

6.5 Nature and composition of immediate packaging

Clear, Glass Type I (Ph.Eur) vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap. Package quantities: 10 ml vials.

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

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 06376/4098

9. DATE OF FIRST AUTHORISATION

19 March 1993

10. DATE OF REVISION OF TEXT

December 2024

Gavin Hall
Approved: 09 December 2024