1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Myodine 25 mg/ml solution for injection for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Nandrolone laurate 25 mg
(equivalent to nandrolone 15 mg)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	104 mg
Arachis oil, refined	

Clear yellowish oily solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

Indicated for use in dogs and cats as an adjunctive treatment for conditions in which anabolic therapy is considered to be beneficial.

3.3 Contraindications

Do not use in pregnant animals (see also section 3.7).
Do not use in animals with hypercalcaemia.
Do not use in animals with androgenic dependent tumours.
Do not use in breeding animals.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

Anabolic therapy is to induce an improvement in clinical signs rather than a cure. The animal should therefore be carefully examined for potential pre-existing disease, and the anabolic therapy should be combined with treatment of this underlying disease, if present.

3.5 Special precautions for use

Special precautions for safe use in the target species:
This veterinary medicinal product contains benzyl alcohol, which has been documented to cause adverse reactions in neonates. For this reason, use of the veterinary medicinal product is not recommended in very young animals.

Special care (particularly in geriatric patients) should be taken when administering the veterinary medicinal product to animals with compromised cardiac or renal function because of the potential of anabolic steroids to increase sodium and water retention.
The veterinary medicinal product should be administered with caution to animals with severe hepatic dysfunction. The liver function of treated animals should be monitored. Complications (e.g. oedema) may occur when administering the veterinary medicinal product to animals with pre-existing cardiac, renal or hepatic disease, in this case treatment must be stopped immediately.
Special care should be taken when administering the veterinary medicinal product to young (growing) animals, since androgens may accelerate epiphyseal closure.
Prolonged administration may cause signs of the androgenic activity to appear, especially in entire female animals.
Steroids may improve glucose tolerance and decrease the need for insulin or other anti-diabetic drugs. Therefore diabetic animals should be monitored carefully and dose adjustment of anti-diabetic drugs might be necessary.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, transient painful, local reactions may occur. Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
This veterinary medicinal 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 veterinary medicinal product can cause eye irritation. Avoid contact with eyes. If the veterinary medicinal 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 veterinary medicinal product. Therefore, the veterinary medicinal product should not be administered by pregnant women or women trying to conceive.
This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to nandrolone, benzyl alcohol or arachis oil (peanut oil) should avoid contact with the veterinary medicinal product.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Dogs and cats:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injection site reaction [a] Behavioural disorder [b] Abnormal urine odour [c]
Undetermined frequency (cannot be estimated from the available data):	Electrolyte disorder [d] Hepatic toxicosis Reproductive tract disorder (decreased number of spermatozoa, abnormal oestrus [e])

[a] As consequence of the oily solution.
[b] Androgenic.
[c] Strong. In cats.

[d] Retention of sodium, calcium, potassium, water, chloride, phosphate.
[e] Oestrus suppression.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Do not use during pregnancy.
The safety of the veterinary medicinal product has not been established during lactation. Use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Anabolic steroids may potentiate the effects of anticoagulants.
The concurrent administration of anabolic steroids with ACTH or corticosteroids may enhance oedema formation.

3.9 Administration routes and dosage

For subcutaneous or intramuscular use.

Dogs and cats, 2 – 5 mg nandrolone laurate per kg bodyweight, corresponding to 0.08 - 0.2 ml veterinary medicinal product per kg bodyweight.
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.
Use a dry sterile needle and syringe to avoid the introduction of contamination during use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QA14AB01

4.2 Pharmacodynamics

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 males and females with equally safe and potent activity.

4.3 Pharmacokinetics

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 the veterinary medicinal product administered (1 mg/kg) was less than the range recommended in the SPC: 2 – 5 mg/kg. The plasma levels after treatment would thus have a somewhat higher peak and slightly longer duration of action.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening the immediate packaging: 70 days.

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light. At low temperatures the veterinary medicinal product may become viscous and turbid. Warming the vial in the hand will return the contents to the normal state.

5.4 Nature and composition of immediate packaging

Cardboard box with 1 clear type I glass vial containing 5 ml with a coated bromobutyl rubber stopper and aluminium cap.
Cardboard box with 1 clear type II glass vial containing 10 ml or 20 ml with a coated bromobutyl rubber stopper and aluminium cap.

Pack sizes:
Box with 1 vial of 5 ml
Box with 1 vial of 10 ml
Box with 1 vial of 20 ml

Multi-pack with 6 vials of 5 ml
Multi-pack with 6 vials of 10 ml
Multi-pack with 6 vials of 20 ml

Multi-pack with 10 vials of 5 ml
Multi-pack with 10 vials of 10 ml
Multi-pack with 10 vials of 20 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10475/027/001

8. DATE OF FIRST AUTHORISATION

28/07/2017

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

28/08/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).