1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Myodine 25 mg/ml solution for injection for dogs and cats (AT, BE, CY, CZ, EL, ES, FR, HR, HU, IE, IT, LU, NL, PT, RO, SI, SK, UK)
Myodine vet 25 mg/ml solution for injection for dogs and cats (DK, EE, FI, IS, LT, LV, NO, PL, SE)
Nandrosol 25 mg/ml solution for injection for dogs and cats (DE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

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

Excipient(s):
Benzyl alcohol (E1519) 104 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear yellowish 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 as an adjunctive treatment for conditions in which anabolic therapy is considered to be beneficial.

4.3 Contraindications

Do not use in pregnant animals (see also section 4.7).
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.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals
This product contains benzyl alcohol, which has been documented to cause adverse reactions in neonates. For this reason, use of the product is not recommended in very young animals.
Special care (particularly in geriatric patients) should be taken when administering the product to animals with compromised cardiac or renal function because of the potential of anabolic steroids to increase sodium and water retention.
The 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 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 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 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.
This 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.

4.6 Adverse reactions (frequency and seriousness)

As with all oily solutions, injection site reactions may occur, which have been reported very rarely in spontaneous reports. A strong abnormal urine odour in cats has been reported very rarely in spontaneous reports.

Possible adverse reactions of anabolic steroids in dogs and cats include retention of sodium, calcium, potassium, water, chloride and phosphate; hepatotoxicity; behavioural androgenic changes and reproductive disturbances (oligospermia, oestrus suppression).
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy and lactation

Pregnancy:
Do not use in pregnant animals

Lactation:
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.

4.8 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.

4.9 Amounts to be administered and administration route

For subcutaneous or intramuscular injection.
Dog and cat, 2-5 mg nandrolone laurate per kg bodyweight, corresponding to 0.08-0.2 ml 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.

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

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

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anabolic steroids, 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 males and females with equally safe and potent activity.

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 the 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Arachis oil, refined

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:	30 months
Shelf-life after first opening of the immediate packaging:	70 days

6.4. Special precautions for storage

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

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal product 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

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:
Date of last renewal:

10 DATE OF REVISION OF THE TEXT