ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Nandrolone laurate 25 mg/ml
(equivalent to nandrolone 15 mg)

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

5 ml
10 ml
20 ml

5. TARGET SPECIES

Dogs, cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For SC, IM use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 70 days
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.
Read the package leaflet before use.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
To be supplied only on veterinary prescription POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 41821/4040

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vials of 5, 10 or 20 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

25 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 ml
10 ml
20 ml

4. ROUTE(S) OF ADMINISTRATION

SC, IM

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 70 days
Once broached use by ……..

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

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

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

Excipients:
Benzyl alcohol (E1519) 104 mg

Clear yellowish oily solution.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in pregnant animals (see also section 12).
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.

6. ADVERSE REACTIONS

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).

If you notice any side effects, even those not already listed in this package leaflet or if you think that the medicine has not worked, please inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

Use a dry sterile needle and syringe to avoid the introduction of contamination during use.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 70 days

12. SPECIAL WARNING(S)

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.

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.

Pregnancy and lactation:
Do not use in pregnant animals .
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.

Overdose (symptoms, emergency procedures, antidotes):
Unduly prolonged dosage, or overdosage, may cause signs of androgenic activity (virilisation) to appear, especially in entire female animals.

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

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2022

15. OTHER INFORMATION

Pack sizes:
Cardboard box with 1 vial of 5 ml, 10 ml or 20 ml.
Multi-pack with 6 vials of 5 ml, 10 ml or 20 ml.
Multi-pack with 10 vials of 5 ml, 10 ml or 20 ml.

Not all pack sizes may be marketed.

Approved 07 June 2022