PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Laurabolin 25 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Nandrolone laurate
Each ml contains 25 mg Nandrolone laurate and 104 mg Benzyl alcohol.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

10 ml

5. TARGET SPECIES

For administration to cats and dogs.

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oily solution for intramuscular or subcutaneous injection.

Swab the septum before removing each dose.
Use a dry sterile needle and syringe.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Pregnant women or women trying to conceive should not administer this product.
Read package leaflet for directions, indications, disposal advice and warnings before use.

10. EXPIRY DATE

Expiry end of:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Protect from light.
Keep container in outer carton.
At low temperature the product may become viscous. Warming the product in the hand will return the contents to the normal state.
Following withdrawal of the first dose use the product within 28 days.
Discard unused material.

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

Read package leaflet before use.

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

[Distribution category]
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

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
MK7 7AJ

Distributor in N. Ireland:
Intervet Ireland Ltd.
Magna Drive, Magna Business Park
City West Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4253

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Laurabolin 25 mg/ml solution for injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each ml contains 25 mg Nandrolone laurate and 104 mg Benzyl alcohol.

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

10 ml

4. ROUTE(S) OF ADMINISTRATION

I.M. / S.C.

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Batch no.:

7. EXPIRY DATE

Expiry end of:
Once broached, use by _____

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

FOR ANIMAL TREATMENT ONLY

To be supplied only on veterinary prescription.
KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.
Target species: cats and dogs.
Keep container in outer carton.

PACKAGE LEAFLET FOR:

Laurabolin 25 mg/ml solution for injection

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

Marketing authorisation holder
MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release
Intervet International B.V.
Wim de Korverstraat
5831 AN Boxmeer
Holland

and

Intervet International GmbH
35 Feldstrasse 1a
85716 Unterschleissheim
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Laurabolin 25 mg/ml, solution for injection

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

Each ml contains:
Active substance:

Nandrolone laurate	25 mg
equivalent to nandrolone	15 mg

Other substance:

Benzyl alcohol	10.4% w/v

Solution for injection. Light yellow oily solution.

4. INDICATION(S)

Nandrolone is a testosterone derivative which can be used in the supportive

management of chronic renal failure.

5. CONTRAINDICATIONS

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.

6. ADVERSE REACTIONS

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).

7. TARGET SPECIES

Dogs and cats.

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

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.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

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.
Following withdrawal of the first dose, use the product within 28 days. When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.
Keep the container in the outer carton.
Keep out of the sight and reach of children.

12. SPECIAL WARNING(S)

Special warnings for each target species:
To be used with caution in known cases of hepatic impairment.
Special precautions for use in animals:
None.
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.Pregnancy:
Laurabolin is contra-indicated in pregnant animals.
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
Overdose:
No specific treatment or antidote recommended.
Incompatibilities:
None known.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

June 2021

15. OTHER INFORMATION

For animal treatment only.

Pack sizes

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

Legal category

POM-V
To be supplied only on veterinary prescription.

Marketing authorisation number

Vm 01708/4253

Distributor in Northern Ireland: Intervet Ireland Ltd. Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland.

Approved 16 June 2021