# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARTONBOX**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Leventa 1 mg/mL oral solution for dogs

Levothyroxine sodium

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Levothyroxine sodium (as multihydrate) 1 milligram

(equivalent to 0.97 milligram levothyroxine)

Ethanol 96%

## 3. PHARMACEUTICAL FORM

Oral solution

## 4. PACKAGE SIZE

Carton box with one 30 mL bottle and one 1 mL oral dosing syringe

Carton box with six 30 mL bottles and six 1 mL oral dosing syringes

Carton box with twelve 30 mL bottles and twelve 1 mL oral dosing syringes

## 5. TARGET SPECIES

Dogs

## 6. INDICATION

Treatment of hypothyroidism in dogs.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use. In thyroid hormone replacement therapy with L-thyroxine, the dose rate and regime have to be tailored individually to each dog. A starting dose rate of 20 microgram L-thyroxine sodium/kg once daily is recommended. At re-examination four weeks later, dose adjustment should be performed based on the clinical response to treatment and thyroid hormone concentration evaluated 4-6 hours after the administration of Leventa. Further assessment of hormonal responses and dose adjustment may be repeated at 4 week intervals if required.

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

Not applicable.

## 9. SPECIAL WARNING(S), IF NECESSARY

In the case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Read the package leaflet before use.

## 10. EXPIRY DATE

*[For terms on Batch number and Expiry date see Appendix IV]*

<EXP {month/year}>
Once opened, use within 6 months

## 11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator. Store in the original container.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 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.

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

Keep out of the reach and sight of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4527

## 17. MANUFACTURER'S BATCH NUMBER

Batch number.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING**

**BOTTLE/30 mL**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Leventa 1 mg/mL oral solution for dogs

Levothyroxine sodium

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Levothyroxine sodium (as multihydrate) 1 milligram

(equivalent to 0.97 milligram levothyroxine)

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

30 mL.

## 4. ROUTE(S) OF ADMINISTRATION

For oral use

## 5. WITHDRAWAL PERIOD

Not applicable.

## 6. BATCH NUMBER

<Batch> <Lot> <BN> {number}

## 7. EXPIRY DATE

<EXP {month/year}>
<Once broached,/opened, use by…>

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

Leventa 1 mg/mL oral solution for dogs

## 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 for the batch release:

Intervet Productions
Rue de Lyons
27460 Igoville
France

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Leventa 1 mg/mL oral solution for dogs
Levothyroxine sodium

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

Each mL contains 1 mg Levothyroxine sodium (as multihydrate) (equivalent to 0.97 mg levothyroxine) and 0.15 ml ethanol 96% as antimicrobial preservative).
The oral solution is a clear, slight reddish coloured solution.

## 4. INDICATION

Treatment of hypothyroidism in dogs

## 5. CONTRAINDICATIONS

The product should not be used in dogs with hyperthyroidism or uncorrected adrenal insufficiency (hypoadrenocorticism).
Do not use in dogs with hypersensitivity to levothyroxine sodium or to any of the excipients.

## 6. ADVERSE REACTIONS

Adverse reactions associated with treatment with L-thyroxine sodium are primarily those of hyperthyroidism due to therapeutic overdose. They include body weight loss, hyperactivity, increased heart rate, thirst, increased urination, increased appetite,

vomiting and diarrhoea. Transient, self-resolving skin reactions such as mild to moderate scale formation may occur.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Dogs.

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

For oral use.

In thyroid hormone replacement therapy with L-thyroxine, the dose rate and regime have to be tailored individually to each dog. A starting dose rate of 20 microgram L-thyroxine sodium/kg
(0.2 mL per 10 kg bodyweight) once daily is recommended. Four weeks later, dose adjustment should be performed based on the clinical response to treatment and thyroid hormone concentration evaluated 4-6 hours after administration of the product. Further assessment of hormonal responses and dose adjustment may be repeated at 4 week intervals if required.

A maintenance dose rate between 10 and 40 microgram/kg body weight once daily is generally sufficient. The dosage suitable to treat your dog is decided by your prescribing veterinarian. Depending on the dosage and on the body weight of your dog, the volume (in mL) of the product to be administered once daily can be estimated using the following table:

| **Body weight (kg)** | **Dosage (microgram/kg)** | | | |
|---|---|---|---|---|
| | **10** | **20** | **30** | **40** |
| | **Volume of the product (mL)** | | | |
| **5** | 0.05 | 0.10 | 0.15 | 0.20 |
| **10** | 0.10 | 0.20 | 0.30 | 0.40 |
| **15** | 0.15 | 0.30 | 0.45 | 0.60 |
| **20** | 0.20 | 0.40 | 0.60 | 0.80 |
| **25** | 0.25 | 0.50 | 0.75 | 1.00 |
| **30** | 0.30 | 0.60 | 0.90 | 1.20 |
| **35** | 0.35 | 0.70 | 1.05 | 1.40 |
| **40** | 0.40 | 0.80 | 1.20 | 1.60 |
| **45** | 0.45 | 0.90 | 1.35 | 1.80 |
| **50** | 0.50 | 1.00 | 1.50 | 2.00 |

The dose for dogs weighing more than 50 kg should be calculated according to bodyweight in the same way.

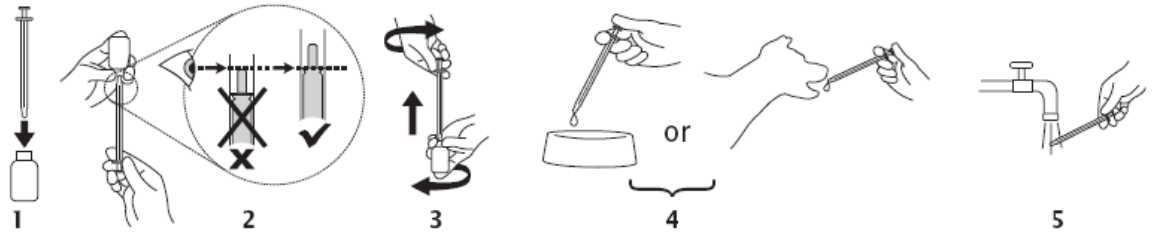
Once a suitable dose rate and regime have been established, it is recommended to recheck every
6 months that thyroid hormone concentrations are appropriate.

Metabolic signs such as lethargy usually improve within two weeks after the onset of treatment whereas skin and coat changes may require 6 weeks or more of treatment before improvement is seen.

## 9. ADVICE ON CORRECT ADMINISTRATION

The product should be administered at the same time every day. The absorption of L-thyroxine is influenced by food. Thus, L-thyroxine should be preferably administered 2-3 hours prior to feeding. If not, the feed given (type and amount) should be standardized.

Instruction for use of the oral syringe:
Open the bottle. (1) Attach the dosing syringe to the bottle by gently pushing the end of the syringe onto the insert in the bottle. (2) Turn the bottle/syringe upside down and draw the solution into the syringe by pulling the plunger out until the edge of the ring on the end of the plunger coincides with the expected volume or body weight in kilograms. (3) Turn the bottle/syringe right way up and remove the syringe from the insert. (4) After administering the product, (5) clean the syringe by flushing with clean water and allow to dry naturally.




## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store in a refrigerator (+2°C to +8°C). Store in the original container.
After first opening, use the product within 6 months.

Do not use after the expiry date which is stated on the label after Exp.

## 12. SPECIAL WARNING(S)

The product should be used with caution in dogs with heart disease, diabetes mellitus or treated adrenal insufficiency (hypoadrenocorticism). For these dogs, gradual introduction of levothyroxine therapy, starting with 25% of the normal dose and increasing by 25% increments every two weeks until optimal stabilisation is achieved is recommended.

The clinical diagnosis of hypothyroidism should be confirmed by laboratory tests.

Use in pregnant or lactating bitches or animals intended for future breeding has not been evaluated. Pregnant bitches receiving treatment should be monitored on a regular basis from conception until several weeks after delivery, as dose requirements may change during pregnancy and lactation.

Drug interactions
L-thyroxine absorption may be impaired by the concomitant administration of antacids, e.g. aluminium or magnesium salts or calcium carbonate, or ferrous sulphate, and sucralfate. Therefore, concomitant administration of Leventa with the above mentioned compounds should be avoided. At least 2 hours should elapse between administration of Leventa and such products.

The therapeutic response to Leventa may be altered by any compound that influences thyroid hormone metabolism and disposition (e.g. drugs displacing protein-binding site, modifying serum thyroxine-binding globulin concentration, or altering hepatic degradation of thyroxine or peripheral conversion of thyroxine to triiodothyronine). Thus, in case of concomitant administration of Leventa with a compound exhibiting one of these properties, it is recommended to recheck that thyroid hormone concentrations are appropriate and to adjust the dose of Leventa accordingly if needed.

Conversely, L-thyroxine supplementation may affect the pharmacokinetics and activity of concurrent therapies. In diabetic dogs treated with insulin, L-thyroxine supplementation may alter insulin requirements. In dogs with cardiac insufficiency, therapeutic response to cardiac glycosides may be decreased by L-thyroxine supplementation. Therefore, if treated with any of these compounds, dogs should be monitored carefully during initiation of treatment with Leventa.

Please inform your veterinary surgeon if your dog receives any other medication before or during treatment with Leventa.

Overdose
Clinical signs of overdose with L-thyroxine include body weight loss, hyperactivity, increased heart rate, thirst, increased urination, increased appetite and diarrhoea. These signs are generally mild and fully reversible. Overdose may influence some blood parameters. For further details, please ask your veterinary surgeon.

User safety
In the case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Note: this product contains a high concentration of L-thyroxine sodium and may present a risk to humans if ingested. Wash hands after use.
In case of eye contact, flush immediately with water.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

## 15. OTHER INFORMATION

Presentations:
Carton box with one 30 mL bottle and one 1 mL oral dosing syringe
Carton box with six 30 mL bottles and six 1 mL oral dosing syringes
Carton box with twelve 30 mL bottles and twelve 1 mL oral dosing syringes

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.