PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thyforon flavoured 800 microgram tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
778 microgram levothyroxine equivalent to 800 microgram levothyroxine sodium

3. PACKAGE SIZE

50 tablets
250 tablets

4. TARGET SPECIES

Dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 ºC.
Return any divided tablet to the opened blister and use within 4 days.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.

14. MARKETING AUTHORISATION NUMBER

Vm 16849/4037

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thyforon flavoured

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Levothyroxine sodium 800 microgram/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Thyforon flavoured 200 microgram tablets for dogs
Thyforon flavoured 400 microgram tablets for dogs
Thyforon flavoured 600 microgram tablets for dogs
Thyforon flavoured 800 microgram tablets for dogs

2. Composition

Each tablet contains:

Active substances:
194 microgram levothyroxine equivalent to 200 microgram levothyroxine sodium
389 microgram levothyroxine equivalent to 400 microgram levothyroxine sodium
583 microgram levothyroxine equivalent to 600 microgram levothyroxine sodium
778 microgram levothyroxine equivalent to 800 microgram levothyroxine sodium
Off white round tablet with brown spots, quadrisect with side scores. The tablets may be divided into halves or quarters.

3. Target species

Dogs.

4. Indications for use

For the treatment of hypothyroidism (underproduction of thyroid hormone) in dogs.

5. Contraindications

Do not use in dogs suffering from uncorrected adrenal insufficiency.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

The diagnosis of hypothyroidism should be confirmed with appropriate tests.

Special precautions for safe use in the target species:
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of animals.

The increased metabolic rate resulting from treatment with levothyroxine sodium may place undue stress on a poorly functioning heart, causing signs of heart failure. Hypothyroid dogs suffering from hypoadrenocorticism (Addison's disease) have a decreased ability to metabolise levothyroxine sodium and therefore an increased risk of overdose. Dogs with concurrent hypoadrenocorticism and hypothyroidism should be stabilised with glucocorticoid and mineralocorticoid treatment prior to treatment with levothyroxine sodium to avoid precipitating a hypoadrenocortical crisis. After this, thyroid tests should be repeated, then gradual introduction of the levothyroxine sodium therapy, starting with 25% of the normal dose, increasing by 25% increments every fortnight until optimal stabilisation is achieved is recommended.
Gradual introduction of therapy is also recommended for dogs with other concurrent illnesses; particularly in dogs with cardiac disease, diabetes mellitus and kidney or liver disease.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Any unused tablet portion(s) should be returned to the open blister for use at the next administration. Wash hands after administering the tablets. Pregnant women should handle the veterinary medicinal product with caution. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
To the physician: this veterinary medicinal product contains a high concentration of L-thyroxine sodium and may present a risk to humans, in particular children, if ingested.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in pregnant or lactating bitches. However, levothyroxine is produced naturally in the body and thyroid hormones are essential for the developing foetus, especially during the first period of pregnancy. Hypothyroidism during pregnancy may result in major complications such as foetal death and a poor outcome at birth. Maintenance dose of levothyroxine sodium may need adjustment during pregnancy. Pregnant bitches should therefore be monitored on a regular basis from conception until several weeks after delivery by the veterinarian.
Tell your veterinarian either if you intend to use your dog for breeding purposes or if your dog is pregnant.

Interaction with other medicinal products and other forms of interaction:
A variety of drugs may impair plasma or tissue binding of the thyroid hormones or alter thyroid hormone metabolism (e.g. barbiturates, antacids, anabolic steroids, diazepam, furosemide, mitotane, phenylbutazone, phenytoin, propranolol, large doses of salicylates and sulphonamides). When treating dogs that are receiving concurrent medication the properties of these drugs should be taken into consideration. Tell your veterinarian if your dog is already being treated with any other veterinary medicinal product.
Oestrogens may increase thyroid requirements.
Ketamine may cause tachycardia and hypertension when used in patients receiving thyroid hormones. The effect of catecholamines and sympathomimetics is increased by levothyroxine. An increase in the dosage of digitalis may be necessary in a patient that had previously stabilised congestive heart failure and that is placed on thyroid hormone supplementation.

Following treatment of hypothyroidism in dogs with concurrent diabetes, careful monitoring of diabetic control is recommended.
Most dogs on long term high-dose, daily glucocorticoid therapy will have very low or undetectable serum T_4 concentrations, as well as subnormal T_3 values.

Overdose:
Following administration of overdoses signs of toxicity relating to increased levels of thyroid hormone could occur. Toxicity as a side effect of mild over-supplementation is uncommon in dogs, owing to the canine ability to break down and excrete thyroid hormones. Single overdose up to 3-6x the recommended dose does not pose a threat even to the healthy dog with normal thyroid function, and no actions are necessary.
In case of accidental intake of large amounts of the veterinary medicinal product absorption can be decreased by induction of vomiting and oral administration of both activated charcoal and magnesium sulphate once.
Following long term over-supplementation, clinical signs of excess thyroid hormone such as increased thirst and urination, panting, weight loss without loss of appetite, and either or both increased heart rate and nervousness may theoretically occur. The presence of these signs should result in evaluation of T_4 serum concentrations to confirm the diagnosis, and immediate discontinuance of the supplementation. Once the signs have abated (days to weeks), the thyroid dosage has been reviewed, and the animal has fully recovered, a lower dosage may be instituted, with the animal being monitored closely.
In case of overdose, contact your veterinarian.

7. Adverse events

Dogs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Weight loss[a,b], Polydipsia (increased thirst)[a], Polyphagia (excessive food intake)[a] Hyperactivity[a], Excitation[a] Panting[a] Tachycardia (increased heart rate)[a] Polyuria (increased urination)[a] Hypersensitivity reaction (Pruritus)

[a] Adverse reactions of thyroid hormones are generally associated with excessive dosage and correspond to the symptoms of hyperthyroidism, see also section Special warnings: Overdose.

[b] Without loss of appetite.

Restoration of physical activity may unmask or intensify other health-related problems, such as arthritis. Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the

marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Oral use.
The recommended starting dosage of levothyroxine sodium is 10 µg/kg body weight orally every 12 hours. Because of variability in absorption and metabolism, the dosage may require alterations before a complete clinical response is observed. The initial dosage and frequency of administration are merely a starting point. Therapy has to be highly individualised and tailored to the requirements of the individual dog, in accordance with monitoring by the veterinarian.

In the dog, absorption of levothyroxine sodium may be affected by the presence of food. The timing of treatment and its relation to feeding should therefore be kept consistent from day to day.

When initiating dosing of dogs weighing less than 5 kg bodyweight, a quarter of one 200 µg tablet should be administered once daily. Such cases should be monitored carefully by your veterinarian.

To adequately monitor therapy, trough values (just prior to treatment) and peak values (about three hours after dosing) of plasma T_4 can be measured. In adequately dosed dogs peak plasma concentration of T_4 should be in the high-normal range (approximately 30 to 47 nmol/l) and trough values should be above approximately 19 nmol/l. If T_4 levels are outside this range the levothyroxine sodium dose can be adjusted in 50 to 200 µg increments using the appropriate strength(s) of tablets until the patient is clinically euthyroid and serum T_4 is within the reference range. Plasma T_4 levels can be retested two weeks after change of dosage, but clinical improvement is an equally important factor in determining individual dosage and this will take four to eight weeks. When the optimum replacement dose has been attained, clinical and biochemical monitoring may be performed every 6 – 12 months.

9. Advice on correct administration

To break a tablet accurately and easily, place the tablet score side up and apply pressure with your thumb.

To break the tablet in two parts; hold one half of the tablet down and press down the other half.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C
Return any divided tablet to the opened blister and use within 4 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the blister after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 16849/4034
Vm 16849/4035
Vm 16849/4036
Vm 16849/4037

The veterinary medicinal product is packaged in a blister [Aluminium (20µm) - PVC/PE/PVDC (250/30/90) white].

10 tablets per blister, 5 or 25 blisters per carton, 50 or 250 tablets per carton.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder:
Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:
Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

Dales Pharmaceuticals Limited
Snaygill Industrial Estate, Keighley Road, Skipton
North Yorkshire, BD23 2RW
United Kingdom

Genera d.d.
Svetonedeljska cesta 2, Kalinovica
10436 Rakov Potok
Croatia

Only the site testing and releasing the batches will be mentioned on the printed leaflet.

Local representatives and contact details to report suspected adverse events:
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel.: +44 (0)1939 211200

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

17. Other information

POM-V

Gavin Hall
Approved: 05 December 2025