PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{NATURE/TYPE} CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thyforon flavoured 800 microgram tablets for dogs
Levothyroxine sodium

2. STATEMENT OF ACTIVE SUBSTANCES

One tablet contains:
Active substance:
800 microgram levothyroxine sodium per tablet equivalent to 778 microgram levothyroxine

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

50 tablets /250 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

For treatment of hypothyroidism in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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.

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

Eurovet Animal Health B.V., Handelsweg 25, 5531 AE Bladel, The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 16849/4037

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE} BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thyforon flavoured 800 microgram tablets for dogs
Levothyroxine sodium

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health B.V.

3. EXPIRY DATE

Exp: {month/year}

4. BATCH NUMBER

Lot: {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR

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

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

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

Manufacturer's 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 Inc.
Svetonedeljska cesta 2, Kalinovica
10436 Rakov Potok, Croatia

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

2. 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

Levothyroxine sodium

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

One tablet contains:
Active substance:
200 microgram levothyroxine sodium per tablet equivalent to 194 microgram levothyroxine
400 microgram levothyroxine sodium per tablet equivalent to 389 microgram

levothyroxine
600 microgram levothyroxine sodium per tablet equivalent to 583 microgram levothyroxine
800 microgram levothyroxine sodium per tablet equivalent to 778 microgram levothyroxine
Off white round tablet with brown spots, quadrisect with side scores. The tablets may be divided into halves or quarters.

4. INDICATION

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

5. CONTRAINDICATIONS

Do not use in dogs suffering from uncorrected adrenal insufficiency.
Do not use in cases of known hypersensitivity to levothyroxine sodium or any of the excipients.

6. ADVERSE REACTIONS

Restoration of physical activity may unmask or intensify other health-related problems, such as arthritis. Adverse reactions of thyroid hormones are generally associated with excessive dosage and correspond to the signs of excess thyroid hormone e.g. increased thirst and urination, weight loss without a loss of appetite, excessive food intake, panting, hyperactivity, excitability and increased heart rate.
Hypersensitivity reactions (pruritus) have been reported very rarely

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s)) during the course of one treatment)
- 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 you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

For oral administration.
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.

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.

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

None

10. WITHDRAWAL PERIOD

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 WARNINGS

Information for the animal owner
The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of animals.
Tell your veterinarian either if you intend to use your dog for breeding purposes or if your dog is pregnant.
Tell your veterinarian if your dog is already being treated with any other veterinary

medicinal product as this may affect the treatment.
In case of overdose, contact your veterinarian.

Information for the treating veterinarian.
The diagnosis of hypothyroidism should be confirmed with appropriate tests.

Special precautions for use in 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 administrating 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 product with caution. In the case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
To the physician: this 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.

Interactions 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).
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 (symptoms, emergency procedures, antidotes):
Following administration of overdoses signs of toxicity relating to increased levels of thyroid hormone could occur. Toxicity as a side effect of mild oversupplementation 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.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

10 tablets per blister, 5 or 25 blisters per carton, 50 or 250 tablets per carton.
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.

Approved 10 December 2020