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Date: Wednesday, February 18, 2026 13:57

Dechra Veterinary Products

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Thyforon® Flavoured Tablets for Dogs

Species: Dogs

Therapeutic indication:Pharmaceuticals: Hormones and therapeutically related products: Others

Active ingredient: Levothyroxine Sodium

Product: Thyforon® Flavoured Tablets for Dogs

Product index: Thyforon Flavoured Tablets for Dogs

Incorporating:

Qualitative and quantitative composition

Thyforon flavoured 200 microgram tablets for dogs:

One tablet contains: Active substance:

200 microgram levothyroxine sodium (equivalent to 194 microgram levothyroxine)

Thyforon flavoured 400 microgram tablets for dogs:

One tablet contains: Active substance:

400 microgram levothyroxine sodium (equivalent to 389 microgram levothyroxine)

Thyforon flavoured 800 microgram tablets for dogs:

One tablet contains: Active substance:

800 microgram levothyroxine sodium (equivalent to 778 microgram levothyroxine)

Pharmaceutical form

Tablet. Off white round tablet with brown spots, quadrisect with side scores. The tablets may be divided into halves or quarters.

Clinical particulars

Target species

Dogs.

Indications for use

For the treatment of hypothyroidism in dogs.

Contraindications

Do not use in dogs suffering from uncorrected adrenal insufficiency.

Do not use in cases of known hypersensitivity to levothyroxine sodium or to any of the excipients.

Special warnings for each target species

The diagnosis of hypothyroidism should be confirmed with appropriate tests.

Special precautions for use in animals

The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of animals. A sudden increase in demand for oxygen delivery to peripheral tissues, plus the chronotropic effects of levothyroxine sodium, may place undue stress on a poorly functioning heart, causing decompensation and signs of congestive heart failure. Hypothyroid dogs suffering from hypoadrenocorticism have a decreased ability to metabolise levothyroxine sodium and therefore an increased risk of thyrotoxicosis. 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 levothyroxine 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 renal or hepatic dysfunction.

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 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.

Adverse reactions

Restoration of physical activity may unmask or intensify other health-related problems, such as osteoarthrosis. Adverse reactions of thyroid hormones are generally associated with excessive dosage and correspond to the symptoms of hyperthyroidism, including weight loss without loss of appetite, hyperactivity, excitability, panting, tachycardia, polydipsia, polyuria and polyphagia. Hypersensitivity reactions (pruritus) have been reported very rarely. See also *Overdose*.

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).

Use during pregnancy and lactation

The safety of the veterinary medicinal product has not been established in pregnant or lactating bitches. However, levothyroxine is an endogenous substance and thyroid hormones are essential for the developing foetus, especially during the first period of gestation. Hypothyroidism during pregnancy may result in major complications such as foetal death and a poor perinatal outcome. 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.

Interactions

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.

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 compensated 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 chronic high-dose, daily glucocorticoid therapy will have very low or undetectable serum T4 concentrations, as well as subnormal T3 values.

Amounts to be administered and administration route

For oral administration.

The recommended starting dosage of levothyroxine sodium is 10 µg/kg body weight orally every 12 hour. 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. When initiating dosing of dogs weighing less than 5 kg body weight, a quarter of one 200 µg tablet should be administered once daily. Such cases should be monitored carefully. 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 adequately monitor therapy, trough values (just prior to treatment) and peak values (about three hours after dosing) of plasma T4 can be measured. In adequately dosed dogs peak plasma concentration of T4 should be in the high-normal range (approximately 30-47 nmol/l) and trough values should be above approximately 19 nmol/l. If T4 levels are outside this range the levothyroxine dose can be adjusted in 50-200 µg increments using the appropriate strength(s) of tablets until the patient is clinically euthyroid and serum T4 is within the reference range. Plasma T4 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.

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.

Overdose

Following administration of overdoses thyrotoxicosis could occur. Thyrotoxicosis as a side effect of mild over-supplementation is uncommon in dogs, owing to the canine ability to catabolize and excrete thyroid hormones. 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.

Overdoses of three up to six times label recommended starting dose for 4 consecutive weeks in healthy, euthyroid dogs resulted in no significant clinical signs that could be attributed to treatment. Single overdose up to 3-6x the recommended dose does not pose a threat to the dog, and no actions are necessary. However, following chronic over-supplementation, clinical signs of hyperthyroidism such as polydipsia, polyuria, panting, weight loss without anorexia, and either or both tachycardia and nervousness may theoretically occur. The presence of these signs should result in evaluation of T4 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.

Pharmacological particulars

Pharmacotherapeutic group: Thyroid hormones

ATCvet code: QH03AA01

Pharmacodynamic properties

Pharmacologically levothyroxine is classified as a hormonal preparation that replaces deficient endogenous hormones.

Levothyroxine T4 is converted to triiodothyronine T3. T3 acts on cellular processes via specific ligand-receptor interactions with the nucleus, the mitochondria, and the plasma membrane. Interaction of T3 with binding sites leads to augmented transcription of DNA or modulation of RNA, thus influencing protein synthesis and enzyme action.

Thyroid hormones act on many different cellular processes. In developing animals and human beings, they are crucial determinants of normal development, especially in the central nervous system. Thyroid supplementation increases basal cellular metabolism and oxygen consumption thereby affecting the function of virtually all organ systems.

Pharmacokinetic properties

Some dogs appeared to consistently either absorb L-thyroxine better and/or eliminate it more slowly than do other dogs. Furthermore absorption and elimination rate is influenced by daily intake of levothyroxine sodium (high absorption/low elimination in case of low intake and *vice versa* in case of high intake). The variability in pharmacokinetic parameters between individual dogs is considerable and, although the presence of food may affect absorption, it is considered to have a minor effect on the parameters overall. Absorption is relatively slow and incomplete: In most cases Tmax occurs between 1-5 hours after oral administration, mean Cmax varies more than 3 fold between dogs on the same doses. In adequately dosed dogs the plasma peak approaches or slightly exceeds the upper limit of normal plasma T4 levels, and by the end of 12 hours after oral administration, plasma T4 usually declines to the lower half of the normal range. The rates of disappearance of T4 from the plasma are slowed in hypothyroidism. A large part of the thyroxine is taken up by the liver. L-thyroxine is bound to plasma-proteins and plasma lipoproteins. Part of a dose of thyroxine is metabolised to the more potent triiodothyronine (T3) by deiodination. The process of deiodination continues. These further deiodinated metabolic products (other than T3 and T4) do not have thyromimetic activity. Other pathways of thyroid hormone metabolism include conjugation to form soluble glucuronides and sulphates for biliary or urinary excretion as well as cleavage of the ether linkage of the iodothyronine molecule. In the dog, over 50% of the T4 produced each day are lost in the faeces. The extrathyroidal body stores of T4 are eliminated and replaced in about 1 day.

Pharmaceutical particulars

Excipients

Calcium hydrogen phosphate dihydrate

Cellulose, Microrcrystalline

Sodium Starch Glycolate (type A)

Magnesium stearate

Natural meat flavour

Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Shelf-life of remaining tablet parts: 4 days.

Special precautions for storage

Do not store above 25°C.

Return any divided tablet to the opened blister and use within 4 days.

Immediate packaging

The 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.

Disposal

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

Marketing Authorisation Holder (if different from distributor)

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

Marketing Authorisation Number

Vm 16849/4034: 200 microgram

Vm 16849/4035: 400 microgram

Vm 16849/4037: 800 microgram

Significant changes

Date of the first authorisation or date of renewal

Thyforon flavoured 200 microgram and 400 microgram tablets for dogs: 22 November 2011

Thyforon flavoured 800 microgram tablets for dogs: 23 November 2011

Date of revision of the text

December 2020

Any other information

For animal treatment only. To be supplied only on veterinary prescription. Keep out of the sight and reach of children.

Legal category

Legal category:POM-V

GTIN

GTIN description: Thyforon Flavoured 200 microgram Tablets for Dogs 250 tablets:

GTIN:08714225156771

GTIN description: Thyforon Flavoured 400 microgram Tablets for Dogs 250 tablets:

GTIN:08714225156795

GTIN description: Thyforon Flavoured 800 microgram Tablets for Dogs 250 tablets:

GTIN:08714225156832