Thyforon® Flavoured

200, 400, 600, 800 mg tablets for dogs

UK IE

Marketing authorisation holder:
Eurovet Animal Health BV
Handelsweg 25, NL-5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:
Eurovet Animal Health BV
Handelsweg 25, NL-5531 AE Bladel
The Netherlands
Dales Pharmaceuticals Limited
Snaygill Industrial Estate, Keighley Road, Skipton
North Yorkshire, BD23 2RW, United Kingdom

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

Statement of the active substance and other ingredients: One tablet contains:
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.

Indications: For the treatment of hypothyroidism (under production of thyroid hormone) in dogs.
Contraindications: Do not use in dogs suffering from uncorrected adrenal insufficiency.
Do not use in cases of known hypersensitivity to levothyroxine sodium.

Adverse reactions: Restoration of physical activity may unmask or intensify other 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 and panting. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

Target species: Dogs.

Dosage for each species, route and method of 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 body weight, a quarter of one 200 µg tablet should be administered once daily. Such cases should be monitored carefully by your veterinarian.

Advice on correct administration: Tablets can be divided into equal halves or quarters to ensure accurate dosing.
Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.
Equal halves: Press down with your thumbs on both sides of the tablet.
Equal quarters: Press down with your thumb in the middle of the tablet.

Withdrawal period: Not applicable.
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.
Expiry date: Do not use after the expiry date stated on the carton and the blister after EXP.

Special warnings:
Tell your veterinarian if your dog is suffering from concurrent illnesses, particularly Addison's disease, diabetes mellitus, heart disease or kidney or liver disease.
Use during pregnancy:
Tell your veterinarian either if you intend to use your dog for breeding purposes or if your dog is pregnant.
Interactions:
Tell your veterinarian if your dog is already being treated with any other veterinary medicinal product as this may affect the treatment.
Overdose:
In case of overdose, contact your veterinarian.
Special precautions to be taken by the person administrating the veterinary medicinal product:
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. Note: This product contains a high concentration of L-thyroxine sodium and may present a risk to humans, in particular children, if ingested.

Information for the treating veterinarian:
The diagnosis of hypothyroidism should be confirmed with appropriate tests.
Therapeutic monitoring:
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 to 47 nmol/l) and trough values should be above approximately 19 nmol/l. If T4 levels are outside this range the levothyroxine sodium dose can be adjusted in 50 to 200 µg increments 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.
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.
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).
Estrogens may increase thyroid requirements.
Ketamine may cause tachycardia and hypertension when used in patients receiving thyroid hormones. The effect of catecholamines and sympatiomimetics 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 T4 concentrations, as well as subnormal T3 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 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.
Pregnancy:
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.

Special precautions for the disposal of unused product or waste materials:
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Date on which the package leaflet was last approved: 20 August 2014

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 animal treatment only. To be supplied only on veterinary prescription.

UK: POM Prescription Only Medicine - Veterinarian	Thyforon flavoured 200 microgram tablets for dogs: Vm 16849/4034 Thyforon flavoured 400 microgram tablets for dogs: Vm 16849/4035 Thyforon flavoured 600 microgram tablets for dogs: Vm 16849/4036 Thyforon flavoured 800 microgram tablets for dogs: Vm 16849/4037
IE: POM Prescription Only Medicine	Thyforon flavoured 200 microgram tablets for dogs: VPA 10989/060/001 Thyforon flavoured 400 microgram tablets for dogs: VPA 10989/060/002 Thyforon flavoured 600 microgram tablets for dogs: VPA 10989/060/003 Thyforon flavoured 800 microgram tablets for dogs: VPA 10989/060/004

Veterinary medicinal product authorised for use in UK and Ireland.

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