<PARTICULARS TO APPEAR ON THE OUTER PACKAGE>
<PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE>

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forthyron 200 microgram tablet / Forthyron 400 microgram tablet
Levothyroxine sodium

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Composition
Active Substance per tablet:
Levothyroxine sodium 200 µg / 400 µg

3. PHARMACEUTICAL FORM

------- {not repeated, see above and below}

4. PACKAGE SIZE

50 / 250 / 500 tablets
10 tablets per blister

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

-------- { not applicable}

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Tablet portions can be kept for 4 days in the blister pack.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C

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

------{national item}

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

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel, the Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 16849/4005 – 200 Microgram Tablet
Vm 16849/4006 – 400 Microgram Tablet

17. MANUFACTURER'S BATCH NUMBER

Lot{number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forthyron 200 microgram tablet / Forthyron 400 microgram tablet
Levothyroxine sodium

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV

3. EXPIRY DATE

Exp {month/year}

4. BATCH NUMBER

{number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Forthyron 200 microgram tablet
Forthyron 400 microgram tablet

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

Eurovet Animal Health BV, Handelsweg 25, 5531 AE Bladel, the Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Forthyron 200 microgram tablet
Forthyron 400 microgram tablet
Forthyron vet. (Denmark, Sweden, Finland)
Levothyroxine sodium

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

Composition
Active substance per tablet:
Levothyroxine sodium 200 microgram or 400 microgram

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in dogs suffering from uncorrected adrenal insufficiency.

6. ADVERSE REACTIONS

Restoration of physical activity may unmask or intensify other problems, such as arthritis. Adverse effects 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.

7. TARGET SPECIES

Dogs

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

Dosage and 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.

9. ADVICE ON CORRECT ADMINISTRATION

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10. WITHDRAWAL PERIOD

------- {Not applicable}

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 25 °C
Tablet portions can be kept for 4 days in the blister pack.
Expiry Date: Do not use after the expiry date stated on the carton and the blister after Exp (month / year).

12. SPECIAL WARNING(S)

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 intent to breed with your dog or 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

Operator warnings
Wash hands after administering the tablets. Pregnant women should handle the product with caution.

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

Disposal advice
Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2009

15. OTHER INFORMATION

Forthyron 200 microg: MAH number
Forthyron 400 microg: MAH number

Distributed by …
10 Tablets per blister, 5, 25, or 50 blisters per carton, 50, 250 or 500 tablets per carton.
Not all pack sizes may be marketed.

Legal category: POM Prescription Only Medicine

Information for the treating veterinarian.

The diagnosis 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 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 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.

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 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, phenyotin, propranolol, large doses of salicylates and sulphonamides).
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.
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.
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 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 tablets 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.

Pregancy
The safety of use of the product during pregnancy has not been established through special reproduction studies. 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 base from conception until several weeks after delivery by the veterinarian.