Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Soloxine 0.1 mg Tablet

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Levothyroxine Sodium 0.10 mg

Excipients

Tartrazine E102 0.334 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Small elliptical yellow tablets.
Scored on the face of each tablet, strength in milligrams to the right and the word SOLOXINE on the reverse.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

For the long term treatment of thyroid insufficiency in dogs.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredient.
Do not use in animals suffering from thyrotoxicosis or uncorrected adrenal insufficiency

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Appropriate laboratory tests should be conducted to confirm the diagnosis and ensure correct dosage.

Caution should be exercised in the treatment of dogs with clinically significant cardiac disease, hypertension or any disease rendering the animal susceptible to sharply increased metabolic rate. In such cases, consideration should be given to reducing the starting dose, increasing the dose at intervals whilst monitoring all clinical signs. Dogs with concurrent hypoadrenocorticism should be stabilised witth apprpriate steroid therapy before commencing treatment with levothyroxine sodium.

The effects of thyroxine therapy are slow in being manifested

Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of accidental ingestion, seek medical advice immediately and show the doctor the label.
Wash hands after use.

Other precautions

None

4.6 Adverse reactions (frequency and seriousness)

When administered at an appropriate dose there should not be any adverse effects associated with therapy.
Thyrotoxicosis is unusual, but may develop in dogs receiving high doses or in those with impaired metabolism (i.e. renal or hepatic insufficiency).

Clinical signs include panting, nervousness, tachycardia, aggressive behaviour, polyuria, polydipsia, polyphagia and weight loss.

4.7 Use during pregnancy, lactation or lay

Can be used during pregnancy and lactation.
The safety of the product has not been tested in special reproduction studies. However , levothyroxine sodium is an endogenous hormone and thyroid hormones are essential for the developing foetus. Hypothyroidism during pregnancy may result in poor foetal and perinatal outcomes. Therefore, hypothyroid bitches intended to be bred should be monitored on a regular basis before, during and after pregnancy as the dose of levothyroxine sodium may need to be adjusted.

4.8 Interaction with other medicinal products and other forms of interaction

In diabetic dogs with concurrent hypothyroidism careful monitoring of diabetic control is recommended once thyroid treatment commences. Dosages of insulin may need to be increased due to thyroid hormone enhancement of glucose absorption, glycogenolysis and gluconeogenesis.

4.9 Amounts to be administered and administration route

The commonly prescribed starting dose is 22 μ/kg bodyweight per day. However, due to individual differences in absorption and metabolism this is frequently too low and doses of up to 44 μg/kg bodyweight per day may be required. The dosage should be adjusted for the individual case based on the clinical response of the patient and laboratory investigations and should be administered daily.

For oral administration.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Chronic overdosage will eventually lead to thyrotoxicosis, manifested by: panting, nervousness, tachycardia, aggressive behaviour, polyuria, polydipsia, polyphagia and weight loss.

4.11 Withdrawal Period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Thyroid Hormones
ATC Vet Code: QH03AA01

5.1 Pharmacodynamic properties

Levothyroxine is a synthetic homologue of the naturally occurring thyroid hormone, thyroxine (T_4).

Levothyroxine is converted to the more biologically active triiodothyronine (T3). T3 binds *via* specific receptors within the plasma membrane, mitochondria and chromatin resulting in changes in DNA transcription and protein synthesis. Onset of action is therefore slow. Thyroid hormones may act on the cellular processes with effects on the basal metabolic rate, cardiac function and blood flow, lipid and carbohydrate metabolism. They are essential for the normal growth and development of the neurological and skeletal systems.

5.2 Pharmacokinetic properties

Time to reach peak serum concentration takes between 2 and 5 hours and the half life of levothyroxine sodium in dogs following oral administration varies from approximately 6 to 20 hours.

Pharmacokinetic properties, particularly absorption and rate of metabolism, vary markedly between individual dogs, with variations in maximum serum concentration of up to 3 times. Therefore it is important to tailor the dose to the individual dog by regular laboratory and clinical monitoring following commencement of treatment.

Pharmacokinetic trials showed that once daily dosing gave higher peak concentrations than dividing the same dose and giving twice daily.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartrazine E102
Magnesium Stearate
Maize Starch Pregelatinised
Microcrystalline Cellulose
Lactose Monohydrate

6.2 Incompatibilities

Not applicable

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light.

6.5 Nature and composition of immediate packaging

High-density, brown, polyethylene bottles containing 250 tablets, hermetically sealed and closed with childproof screw cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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 .

7 MARKETING AUTHORISATION HOLDER

Virbac S.A.,
Virbac 1,
1ére Avenue – 2065 m – L.I.D.
06516 Carros Cedex,
France.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10988/069/002

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 19th January 2007

Date of last renewal: 27th October 2008

10 DATE OF REVISION OF THE TEXT