VIRBAC CORPORATION

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SOLOXINE®

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Virbac

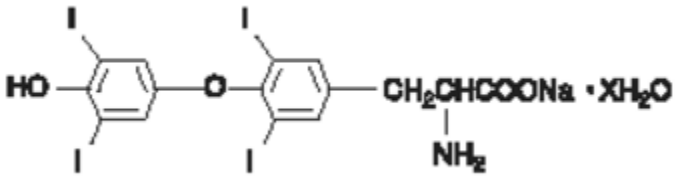
(LEVOTHYROXINE SODIUM TABLETS, USP)

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Description:

Each **SOLOXINE®** (Levothyroxine Sodium, USP) Tablet provides synthetic crystalline levothyroxine sodium (L-thyroxine).

The structural formula for levothyroxine sodium is:



Levothyroxine Sodium Action:

Levothyroxine sodium acts, as does endogenous thyroxine, to stimulate metabolism, growth, development and differentiation of tissues. It increases the rate of energy exchange and increases the maturation rate of the epiphyses. Levothyroxine sodium is absorbed rapidly from the gastrointestinal tract after oral administration.

Following absorption, the compound becomes bound to the serum alpha globulin fraction. For purposes of comparison, 0.1 mg of levothyroxine sodium elicits a clinical response approximately equal to that produced by one grain (65 mg) of desiccated thyroid.

Indications:

Provides thyroid replacement therapy in all conditions of inadequate production of thyroid hormones. Hypothyroidism is the generalized metabolic disease resulting from deficiency of the thyroid hormones levothyroxine (T4) and liothyronine (T3). Soloxine (levothyroxine sodium) will provide levothyroxine (T4) as a substrate for the physiologic deiodination to liothyronine (T3). Administration of levothyroxine sodium alone will result in complete physiologic thyroid replacement.

Canine hypothyroidism is usually primary, i.e., due to atrophy of the thyroid gland. In the majority of cases the atrophy is associated with lymphocytic thyroiditis and in the remainder it is non-inflammatory and as of yet unknown etiology. Less than 10 percent of cases of hypothyroidism are secondary, i.e., due to deficiency of thyroid stimulating hormone (TSH). TSH deficiency may occur as a component of congenital hypopituitarism or as an acquired disorder in adult dogs, in which case it is invariably due to the growth of a pituitary tumor.

Hypothyroidism in the Dog:

Hypothyroidism usually occurs in middle-aged and older dogs although the condition will sometimes be seen in younger dogs of the larger breeds. Neutered animals of either sex are also frequently affected, regardless of age. The following are clinical signs of hypothyroidism in dogs: Lethargy, lack of endurance, increased sleeping; Reduced interest, alertness and excitability; Slow heart rate, weak apex beat and pulse, low voltage on ECG; Preference for warmth, low body temperature, cool skin; Increased body weight; Stiff and slow movements, dragging of front feet; Head tilt, disturbed balance, unilateral facial paralysis; Atrophy of epidermis, thickening of dermis; Surface and follicular hyperkeratosis, pigmentation; Puffy face, blepharoptosis, tragic expression; Dry, coarse, sparse coat, slow regrowth after clipping; Retarded turnover of hair (carpet coat of boxers); Shortening or absence of estrus, lack of libido; Dry feces, occasional diarrhea; Hypercholesterolemia; Normochromic, normocytic anemia; Elevated serum creatinine phosphokinase

Contraindications:

Levothyroxine sodium therapy is contraindicated in thyrotoxicosis, acute myocardial infarction and uncorrected adrenal insufficiency. Use in pregnant bitches has not been evaluated.

Precautions:

The effects of levothyroxine sodium therapy are slow in being manifested. Overdosage of any thyroid drug may produce the signs and symptoms of thyrotoxicosis including, but not limited to: polydipsia, polyuria, polyphagia, reduced heat tolerance and hyperactivity or personality change. Administer with caution to animals with clinically significant heart disease, hypertension or other complications for which a sharply increased metabolic rate might prove hazardous.

Use in pregnant bitches has not been evaluated.

Adverse Reactions:

There are no particular adverse reactions associated with levothyroxine sodium therapy at the recommended dosage levels. Overdosage will result in the signs of thyrotoxicosis listed above under precautions.

Dosage:

The initial recommended dose is 0.1 mg/10 lb (4.5 kg) body weight twice daily. Dosage is then adjusted by monitoring the thyroid blood levels of the dog every four weeks until an adequate maintenance dose is established. The usual maintenance dose is 0.1 mg/10 lb. (4.5 kg) once daily.

DO NOT DISPENSE IN THIS CONTAINER, DISPENSE IN TIGHT, LIGHT-RESISTANT CONTAINERS AS DEFINED IN THE USP.

Administration:

Soloxine tablets may be administered orally or placed in the food.

Dosage forms available:

0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.6 mg, 0.7 mg, 0.8 and 1.0 mg tablets in bottles of 250 and 1,000.

Storage:

Store at controlled room temperature 15°C to 30°C (59°F to 86°F).

KEEP THIS AND ALL MEDICATIONS OUT OF REACH OF CHILDREN.

References:

1. Evinger, J.V., and Nelson, R.W., JAVMA 314. 1984, 185, 314-316.

2. Richard Nelson, DVM; Current Veterinary Therapy X. Edited by R. W. Kirk, W.B. Saunders, Co., Philadelphia, PA 1989 pg:994

3. Edward Feldman, DVM and Richard Nelson, DVM Canine and Feline Endocrinology and Reproduction. W.B. Saunders 1987 pg 82

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For More Information Call 1-800-338-3659

		NDC	ID#	
250 TABLETS (0.1 mg)	Revised April 2006			
250 TABLETS (0.2 mg)	Revised April 2006			
250 TABLETS (0.3 mg)	Revised April 2006			
250 TABLETS (0.4 mg)	Revised April 2006			
250 TABLETS (0.5 mg)	Revised April 2006			
250 TABLETS (0.6 mg)	Revised April 2006			
250 TABLETS (0.7 mg)	Revised April 2006			
250 TABLETS (0.8 mg)	Revised April 2006			
250 TABLETS (1.0 mg)	Revised April 2006	051311-830-25	830250	301640-01
1000 TABLETS (0.1 mg)	Revised May 2006			
1000 TABLETS (0.2 mg)	Revised May 2006			

1000 TABLETS (0.3 mg)	Revised May 2006			
1000 TABLETS (0.4 mg)	Revised May 2006			
1000 TABLETS (0.5 mg)	Revised May 2006			
1000 TABLETS (0.6 mg)	Revised May 2006			
1000 TABLETS (0.7 mg)	Revised May 2006			
1000 TABLETS (0.8 mg)	Revised May 2006			
1000 TABLETS (1.0 mg)	Revised May 2006	NDC 051311-830-10	ID# 830100	301641-01

NAC No.: 10230791