

PALA-TECH™ LABORATORIES, INC.

20633 KAFTAN COURT, LAKEVILLE, MN, 55044

Telephone: 952-985-0746

Toll-Free: 1-888-337-2446

Customer Service: 1-877-402-2357

Technical Service: 1-888-337-2446

Fax: 952-985-7735

Website: www.palatech.com

Email: info@palatech.com

CANINE THYROID CHEWABLE TABLETS



Pala-Tech

(Levothyroxine Sodium, USP)

CAUTION:

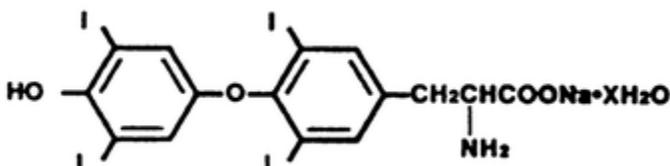
Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Composition: Each scored, round chewable tablet contains either 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.6 mg, 0.7 mg, 0.8 mg, 0.9 mg, or 1.0 mg of Levothyroxine Sodium, USP in a proprietary, highly palatable roast beef and liver flavor base.

DESCRIPTION:

Each tablet, Pala-Tech™ Canine Thyroid Chewable Tablets (Levothyroxine Sodium, USP), 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). Each tablet, Pala-Tech™ Canine Thyroid Chewable Tablets (Levothyroxine Sodium, USP), 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 the 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:

Systemic

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

Musculoskeletal

Stiff and slow movements, dragging of the front feet

Head tilt, disturbed balance, unilateral facial paralysis

Dermatological

Atrophy of the epidermis, thickening of the dermis

Surface and follicular hyperkeratosis, pigmentation

Puffy face, blepharoptosis, tragic expression

Dry, coarse, sparse haircoat, slow regrowth after clipping

Retarded turnover of hair (carpet coat of boxers)

Reproductive

Shortening or absence of estrus, lack of libido

Gastrointestinal

Dry feces, occasional diarrhea

Clinical Pathological

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 to manifest. 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.

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 of levothyroxine is 0.1 mg/10 lb (4.5 kg) body weight twice daily. Dosage is then adjusted by monitoring the post-pill blood level of thyroid hormone in the dog every four weeks until an adequate maintenance dosage is established.

ADMINISTRATION:

Each tablet, Pala-Tech™ Canine Thyroid Chewable Tablets, may be given orally to dogs as a treat, or crumbled over their food at the veterinarian-prescribed dose. If crumbled over food, consumption should be monitored.

HOW SUPPLIED:

Pala-Tech™ Canine Thyroid Chewable Tablets are available in 0.1 mg, 0.2 mg, 0.3 mg, 0.4 mg, 0.5 mg, 0.6 mg, 0.7 mg, 0.8 mg, 0.9 mg and 1.0 mg strength chewable tablets. Tablets are bilaterally scored for all dosage strengths, except for the 1.0 mg strength chewable tablets. The tablets are packaged in bottles of 180 tablets (with childproof caps) and 1,000 tablets.

STORAGE:

Store at controlled room temperature; 15° C to 30° C (59° F to 86° F) and protect from light. Dispense product in this container or another tight, light-resistant container as defined in the USP.

REFERENCES:

Feldman EC, Nelson RW. Canine and Feline Endocrinology and Reproduction. W.B. Saunders, Co., Philadelphia, PA 1996: 68-117.

Nelson RW. Current Veterinary Therapy X. R.W. Kirk (ed), W.B. Saunders, Co., Philadelphia, PA 1989: 993-997.

Evinger JV, Nelson RW. J Am Vet Med Assoc 1984; 185(3): 314-316.

KEEP OUT OF REACH OF CHILDREN

Manufactured for: Pala-Tech™ Laboratories, Inc., *The Science of Palatability™*, Lakeville, MN 55044 USA

www.PALATECH.com

©2011 Pala-Tech™ Laboratories, Inc.

Made in the U.S.A.

Rev. 07-07

NAC No.: 10680052