

THYRO-L- levothyroxine sodium powder
LLOYD, Inc. of Iowa

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Thyro-L®

Indications

For use in horses for correction of conditions associated with low circulating thyroid hormone (hypothyroidism).

Dosage

The suggested initial dose is 0.5 to 3.0 mg levothyroxine sodium (T-4) per 100 pounds body weight (1 to 6 mg per 100 kg) once per day or in divided doses. Response to the administration of Thyro-L should be evaluated clinically until an adequate maintenance dose is established. In most horses, this is usually in the range of 6 to 36 mg (½ to 3 level teaspoons) total daily dose of T-4. Serum T-3 and T-4 values can vary greatly among individual horses on thyroid supplementation. Dosages should be individualized and animals should be monitored daily for clinical signs of hyperthyroidism or hypersensitivity.

Administration

For oral dosing as directed by a veterinarian.

Warning

Use with caution in animals with clinically significant heart disease, hypertension or other complications for which a sharply increased metabolic rate might prove hazardous. Use in pregnant mares has not been evaluated.

Caution

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

Active Ingredient per pound (453.6 g)

Levothyroxine Sodium	0.22% (1,000mg)
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One level teaspoonful contains approximately 12 mg of T-4.

One level tablespoonful contains approximately 36 mg of T-4.

Teaspoon measure included.

IMPORTANT
KEEP OUT OF REACH OF CHILDREN

Store at room temperature and protect from light.
Avoid excessive heat (104°F).

LLOYD, Inc.
Shenandoah, Iowa 51601 U.S.A.

List No. 0481
 1004

PRINCIPAL DISPLAY PANEL - 453.6 g Bottle Label

LLOYD

Net wt: One Pound (453.6 g)

Thyro-L[®]

**Levothyroxine sodium powder, USP
 for horses**

<p>Indications: For use in horses for correction of conditions associated with low circulating thyroid hormone (hypothyroidism).</p> <p>Dosage: The suggested initial dose is 0.5 to 3.0 mg levothyroxine sodium (T-4) per 100 pounds body weight (1 to 6 mg per 100 kg) once per day or in divided doses. Response to the administration of Thyro-L should be evaluated clinically until an adequate maintenance dose is established. In most horses, this is usually in the range of 6 to 36 mg (½ to 3 level teaspoons) total daily dose of T-4. Serum T-3 and T-4 values can vary greatly among individual horses on thyroid supplementation. Dosages should be individualized and animals should be monitored daily for clinical signs of hyperthyroidism or hypersensitivity.</p> <p>Administration: For oral dosing as directed by a veterinarian.</p> <p>Warning: Use with caution in animals with clinically significant heart disease, hypertension or other complications for which a sharply increased metabolic rate might prove hazardous. Use in pregnant mares has not been evaluated.</p> <p>Caution: Federal law restricts this product to use by or on the order of a licensed veterinarian.</p>		<p>Active Ingredient per pound (453.6 g): Levothyroxine Sodium0.22% (1,000 mg)</p> <p>One level teaspoonful contains approximately 12 mg of T-4.</p> <p>One level tablespoonful contains approximately 36 mg of T-4.</p> <p>Teaspoon measure included.</p> <p style="text-align: center;">IMPORTANT KEEP OUT OF REACH OF CHILDREN</p> <p>Store at room temperature and protect from light. Avoid excessive heat (104°F).</p> <p>TAKE TIME  OBSERVE LABEL DIRECTIONS</p> <p>LLOYD, Inc. Shenandoah, Iowa 51601 USA</p> <p>List No. 0481</p> <p>UNVARNISHED AREA</p> 
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THYRO-L

levothyroxine sodium powder

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:11789-048
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVO THYRO XINE SODIUM (UNII: 9J765S329G) (LEVO THYRO XINE - UNII:Q51BO43MG4)	LEVO THYRO XINE SODIUM	1000 mg in 453.6 g

Inactive Ingredients

Ingredient Name	Strength
DIBASIC CALCIUM PHOSPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ETHOXYQUIN (UNII: 9T1410R4OR)	
CALCIUM CARBONATE (UNII: H0G9379FGK)	
MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
LACTOSE (UNII: J2B2A4N98G)	
CORN OIL (UNII: 8470G57WFM)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP)	
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	

Product Characteristics

Color	GRAY (Gray powder)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11789-048-10	453.6 g in 1 BOTTLE, PLASTIC		
2	NDC:11789-048-20	4536 g in 1 PAIL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
UNAPPROVED DRUG OTHER		06/25/1990	

Labeler - LLOYD, Inc. of Iowa (962286535)

Establishment

Name	Address	ID/FEI	Business Operations
LLOYD, Inc. of Iowa		962286535	MANUFACTURE, PACK, LABEL

Establishment

Name	Address	ID/FEI	Business Operations
LLOYD, Inc. of Iowa		007281942	ANALYSIS

Establishment

Name	Address	ID/FEI	Business Operations
Peptido GmbH		327335410	API MANUFACTURE

Revised: 1/2012

LLOYD, Inc. of Iowa