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.

Adminis tration

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

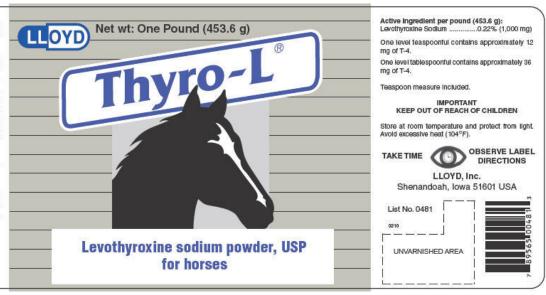
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Administration: For oral dosing as directed by a veterinarian.

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THYRO-L

levothyroxine sodium powder

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Route of Administration

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

reuve ingredient/reuve wither				
h Strength	Basis of Strength	Ingredient Name		
1000 mg in 453.6 g	LEVOTHYROXINE SODIUM	LEVOTHYRO XINE SODIUM (UNII: 9J765S329G) (LEVOTHYRO XINE - UNII:Q51BO43MG4)		

Inactive Ingredients	
Ingredient Name	Strength
DIBASIC CALCIUM PHO SPHATE DIHYDRATE (UNII: O7TSZ97GEP)	
CELLULOSE, MICRO CRYSTALLINE (UNII: OP1R32D61U)	
CALCIUM SILICATE (UNII: S4255P4G5M)	
ALPHA-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
ETHO XYQ UIN (UNII: 9T1410R4OR)	
CALCIUM CARBONATE (UNII: H0 G9 379 FGK)	
MINERAL OIL (UNII: T5L8T28FGP)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	
LACTOSE (UNII: J2B2A4N98G)	
CORN OIL (UNII: 8470G57WFM)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
BUTYLATED HYDRO XYTO LUENE (UNII: 1P9 D0 Z171K)	
CITRIC ACID MONO HYDRATE (UNII: 2968 PHW8 QP)	
BUTYLATED HYDRO XYANISOLE (UNII: REK4960K2U)	

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

P	ackaging			
#	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