

**LEVOTHYROXINE- levothyroxine powder**  
**Butler Animal health Supply, LLC dba Covetrus North America**

*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.*

-----

**Levothyroxine  
Powder**

A palatable supplement for the correction of conditions associated with hypothyroidism in horses and ponies.

**WARNING:**

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

**For animal use only**  
**Keep out of reach of children**

- 1 lb (453.6 g)
- 10 lb (4.5 kg)

**Indications:**

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

**Dosage:**

Doses should be individualized and animals should be monitored daily for clinical signs of hyperthyroidism or hypersensitivity. Suggested initial doses are 1 - 10 mg levothyroxine sodium (T<sub>4</sub>)/100 lb. body weight (2 - 20 mg/100 kg) once per day or in divided doses. Response to the administration of Levothyroxine powder should be evaluated clinically every week until an adequate maintenance dose is established. In most horses, this is usually in the range of 35 to 100 mg total daily dose of T<sub>4</sub> (1 - 3 level tablespoonfuls Levothyroxine powder).

**Administration:**

Levothyroxine powder may be top dressed or mixed with the daily ration.



**Composition:**

Each pound (453.6 g) contains:  
Levothyroxine sodium, USP. . . . . 0.22% (1.0 g)

One level teaspoonful contains 12 mg of T<sub>4</sub>; one level tablespoonful contains 36 mg of T<sub>4</sub>.

**Warning:**

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 mares has not been evaluated.

**Storage:**

Store at controlled room temperature between 15° to 30°C (59°-86°F). Keep lid tightly closed and store in a dry location.

**USE ONLY AS DIRECTED**

**Reorder #017559 (1 lb)**

**Reorder #017560 (10 lb)**

**Questions?** (855) 724-3461

Distributed by:  
Covetrus North America  
400 Metro Place North  
Dublin, OH 43017  
**covetrus.com**

AH-017559-02  
REV: 1019 (1 lb)

AH-017560-02  
REV: 1019 (10 lb)



---

**Indications:** For use in horses and ponies for correction of conditions associated with low circulating thyroid hormone (hypothyroidism).

**Dosage:** Doses should be individualized and animals should be monitored daily for clinical signs of hyperthyroidism or hypersensitivity. Suggested initial doses are 1 - 10 mg levothyroxine sodium (T<sub>4</sub>)/100 lb. body weight (2 - 20 mg/100 kg) once per day or in divided doses. Response to the administration of Levothyroxine powder should be evaluated clinically every week until an adequate maintenance dose is established. In most horses, this is usually in the range of 35 to 100 mg total daily dose of T<sub>4</sub> (1 - 3 level tablespoonfuls Levothyroxine powder).

**Administration:** Levothyroxine powder may be top dressed or mixed with the daily ration.

NDC: 11695-2212-1

## Levothyroxine Powder

A palatable supplement for the correction of conditions associated with hypothyroidism in horses and ponies.

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

**For animal use only**  
**Keep out of reach of children**

**1 lb (453.6 g)**

**Composition:** Each pound (453.6 g) contains:  
Levothyroxine sodium, USP. . . . . 0.22% (1.0 g)  
One level teaspoonful contains 12 mg of T<sub>4</sub>; one level tablespoonful contains 36 mg of T<sub>4</sub>.

**Warning:** 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 mares has not been evaluated.

**Storage:** Store at controlled room temperature between 15° to 30°C (59°-86°F). Keep lid tightly closed and store in a dry location.

**USE ONLY AS DIRECTED**

**Reorder #017559**  
**Questions?** (855) 724-3461

Lot No. / Exp. Date  **TAKE YOUR OBSERVE LABEL COLLECTIONS**

**No Varnish**

Distributed by:  
Covetrus North America  
400 Metro Place North  
Dublin, OH 43017  
covetrus.com

AH-017559-02  
REV: 1019

  
8 40066 50094 2



**Indications:** For use in horses and ponies for correction of conditions associated with low circulating thyroid hormone (hypothyroidism).

**Dosage:** Doses should be individualized and animals should be monitored daily for clinical signs of hyperthyroidism or hypersensitivity. Suggested initial doses are 1 - 10 mg levothyroxine sodium (T<sub>4</sub>)/100 lb. body weight (2 - 20 mg/100 kg) once per day or in divided doses. Response to the administration of Levothyroxine powder should be evaluated clinically every week until an adequate maintenance dose is established. In most horses, this is usually in the range of 35 to 100 mg total daily dose of T<sub>4</sub> (1 - 3 level tablespoonfuls Levothyroxine powder).

**Administration:** Levothyroxine powder may be top dressed or mixed with the daily ration.



Lot No. / Exp. Date

No Varnish

NDC: 11695-2212-2

# Levothyroxine Powder

A palatable supplement for the correction of conditions associated with hypothyroidism in horses and ponies.

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

**For animal use only**  
**Keep out of reach of children**

10 lb (4.5 kg)

**Composition:** Each pound (453.6 g) contains: Levothyroxine sodium, USP ..... 0.22% (1.0 g)

One level teaspoonful contains 12 mg of T<sub>4</sub>; one level tablespoonful contains 36 mg of T<sub>4</sub>.

**Warning:** 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 mares has not been evaluated.

**Storage:** Store at controlled room temperature between 15° to 30°C (59°-86°F). Keep lid tightly closed and store in a dry location.

**USE ONLY AS DIRECTED**

**Reorder #017560**  
**Questions? (855) 724-3461**



Distributed by:  
Covetrus North America  
400 Metro Place North  
Dublin, OH 43017  
covetrus.com

AH-017560-02  
REV: 1019

## LEVOTHYROXINE

levothyroxine powder

### Product Information

<b>Product Type</b>	OTC ANIMAL DRUG	<b>Item Code (Source)</b>	NDC:11695-2212
<b>Route of Administration</b>	ORAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	1.0 g in 453.6 g

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:11695-2212-1	12 in 1 JAR		
1		453.6 g in 1 JAR		
2	NDC:11695-2212-2	4500 g in 1 PAIL		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		11/26/20 19	

**Labeler** - Butler Animal health Supply, LLC dba Covetrus North America (603750329)

## Establishment

Name	Address	ID/FEI	Business Operations
FIRST PRIORITY INCORPORATED		179925722	manufacture, label

Revised: 4/2020

Butler Animal health Supply, LLC dba Covetrus North America