THYROKARE- levothyroxine sodium powder Neogen Corporation-Mercer Rd

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.

THYROKARE EQUINE POWDER

FOR ANIMAL USE ONLY

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 lbs of body weight (1 to 6 mg per 100 kg) once per day or in divided doses. Response to the administration of ThyroKare Powder should be evaluated clinically until an adequate maintenance dose is established. In most horses, the total daily dose of T-4 is in the range of 6 to 36 mg. Serum T-3 and T-4 values can vary greatly among inidividual horses on thyroid supplementation. Dosages should be individualized and animals should be monitored daily for clinical signs of hyperthyroidism or hypersensitivity.

Administration:

ThyroKare Powder can be administered by mixing the daily dose in the concentrate or by top dressing on the grain, preferably rolled or ground. To facilitate the proper adhesion of ThyroKare Powder to the ration, slightly moisten the grain with water or a liquid supplement.

KEEP OUT OF REACH OF CHILDREN

Active Ingredients:

Each pound (453.6 g) contains:Levothyroxine Sodium USP......0.22% (1.0 g) One teaspoon contains:......12 mg of T-4

One tablespoon contains:.....36 mg of T-4

In a palatable limestone base with vanilla flavoring.

Precaution:

Store at 20°-25°C (68°-77°F) with excursions between 15°-30°C (59°-86°F) and protect from light.

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.

Lot No.:

Exp. Date:

Manufactured by:

Neogen Corporation Lexington, KY 40511 859-254-1221 or 800-621-8829 animalsafety.neogen.com Made in USA

PRINCIPAL DISPLAY PANEL 10 pound pail

NDC: 59051-9128-9

ThyroKare™ Equine Powder Levothyroxine Sodium USP

(0.22%)

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

NEOGENVet

Net Contents: 10 lb (4.536 kg)

L3396-0816

FOR ANIMAL USE ONLY

Indications:

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

Dosage

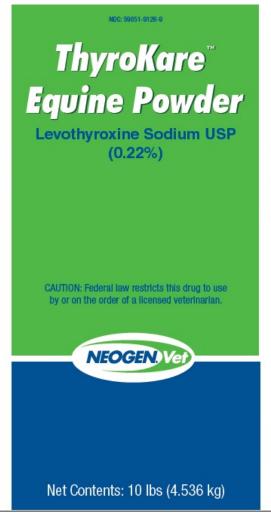
The suggested initial dose is 0.5 to 3.0 mg levothyroxine sodium (T-4) per 100 lbs of body weight (1 to 6 mg per 100 kg) once per day or in divided doses. Response to the administration of ThyroKare Equine Powder should be evaluated clinically until an adequate maintenance dose is established. In most horses, the total daily dose of T-4 is in the range of 6 to 36 mg. 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:

ThyroKare Equine Powder can be administered by mixing the daily dose in the concentrate or by top dressing on the grain, preferably rolled or ground. To facilitate the proper adhesion of ThyroKare Equine Powder to the ration, slightly moisten the grain with water or a liquid supplement.

Lot No.:

Exp. Date:



KEEP OUT OF REACH OF CHILDREN

Active Ingredients:

Each pound (453.6 g) contains:

| Levothyroxine | Sodium USP | 0.22 | 2% (1.0 g) |
|---------------|---------------|------|------------|
| One teaspoon | contains: | 12 | mg of T-4 |
| One tablespoo | n contains: . | 36 | mg of T-4 |

In a palatable limestone base with vanilla flavoring.

Precaution:

Store at 20°-25°C (68°-77°F) with excursions between 15°-30°C (59°-86°F) and protect from light.

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.

Manufactured by: Neogen Corporation Lexington, KY 40511 859-254-1221 or 800-621-8829 animalsafety.neogen.com

Made in USA L3396-0816



THYROKARE

levothyroxine sodium powder

| Product | Inform | nation |
|---------|--------|---------|
| FIUUILL | | IALIUII |

Route of Administration Oral

Active Ingredient/Active Moiety Ingredient Name Basis of Strength LEVOTHYRO XINE SODIUM (UNII: 9J765S329G) (LEVOTHYRO XINE UNII:Q51BO43MG4) LEVOTHYRO XINE SODIUM ANHYDROUS 1 g in 453.6 g

| Product Characteristics | | | |
|-------------------------|---------|--------------|--|
| Color | yello w | Score | |
| Shape | | Size | |
| Flavor | VANILLA | Imprint Code | |
| Contains | | | |

| F | Packaging | | | |
|---|------------------|---------------------|----------------------|--------------------|
| # | Item Code | Package Description | Marketing Start Date | Marketing End Date |
| 1 | NDC:59051-9128-9 | 4536 g in 1 PAIL | | |

| Marketing Information | | | |
|-----------------------|--|----------------------|--------------------|
| Marketing Category | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |
| unapproved drug other | | 11/0 1/20 16 | |
| | | | |

Labeler - Neogen Corporation-Mercer Rd (042125879)

| Establishment | | | |
|------------------------------|---------|-----------|------------------------------|
| Name | Address | ID/FEI | Business Operations |
| Neogen Corporation-Mercer Rd | | 042125879 | analysis, manufacture, label |

| Establishment | | | |
|---------------|---------|-----------|---------------------|
| Name | Address | ID/FEI | Business Operations |
| Peptido GmbH | | 327335410 | api manufacture |

Revised: 11/2018 Neogen Corporation-Mercer Rd