LEVOXINE- levoxine powder First Priority Incorporated

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.

Levoxine 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

INDICATIONS:

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

DOSAGE:

Doses should be individualized and animals should be monitored daily for clincial signs of hyperthyroidism or hypersensitivity. Suggested initial doses are 1-10 mg levothyroxine sodium $(T_4)/100$ lb body weight (2-20 mg/100 kg) once per day or in divided doses. Response to the administration of Levoxine 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_4 (1-3 level tablespoonfuls Levoxine Powder).

INGREDIENTS:

Each pound (453.6 g) contains:

Levothyroxine Sodium USP 0.22% (1.0 g)

One level teaspoonful contains 12 mg of T₄: one level tablespoonful contains 36 mg of T₄.

WARNING: Administer with caution to animals with clincially 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° - 30°C (59° - 86°F). Keep container tightly closed when not in use.

USE ONLY AS DIRECTED



Net Contents:

1 lb (453.6 grams), Reorder No. NS190PC

10 lb (4.5 kg), Reorder No. NS191PC

USE ONLY AS DIRECTED

Made in U.S.A.

Manufactured By:

First Priority, Inc., Elgin, IL 60123

www.prioritycare.com

NOT RETURNABLE IF OUTDATED

1.0 lb (453.6 g) jar



10 lb (4.5 kg) pail



LEVOXINE levoxine powder Product Information Product Type PRESCRIPTION ANIMAL DRUG Item Code (Source) NDC:58829-278 Route of Administration ORAL

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		
LEVOTHYROXINE SODIUM (UNII: 9J765S329G) (LEVOTHYROXINE - UNII:Q51BO43MG4)	LEVOTHYROXINE SODIUM ANHYDROUS	1000 mg in 453.6 g		

Packaging			
# Item Code	Package Description	Marketing Start Date	Marketing End Date
1 NDC:58829-278-16	453.6 g in 1 JAR		
2 NDC:58829-278-07	4500 g in 1 PAIL		

Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
unapproved drug other		08/01/2008		

Labeler - First Priority Incorporated (179925722)

Registrant - First Priority Incorporated (179925722)

Establishment				
Name	Address	ID/FEI	Business Operations	
First Priority Incorporated		179925722	manufacture	

Revised: 9/2018 First Priority Incorporated