RE-COVR- tripelennamine hydrochloride injection
Kinetic Technologies, LLC

RE-COVR™ (tripelennamine hydrochloride injection) 20 mg per mL
Antihistamine

DESCRIPTION:

Tripelennamine hydrochloride is a white, crystalline material which is stable, nonhygroscopic, and readily soluble in water. Tripelennamine hydrochloride is characterized by its capacity to antagonize many of the pharmacologic effects of histamine. **RE-COVR™** (tripelennamine hydrochloride injection) is supplied as a sterile solution in multiple dose vials containing 20 mg of tripelennamine hydrochloride, USP per mL, and may contain sodium hydroxide for pH adjustment.

INDICATIONS:

For use in horses and cattle in conditions in which antihistaminic therapy may be expected to lead to alleviation of some signs of disease. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. See package onsert for complete indications for use.

DOSAGE AND ADMINISTRATION:

Horses: Administer intramuscularly only at a dose of 0.5 mg per lb of body weight (2.5 mL for each 100 lbs of body weight). This dose may be repeated in 6-12 hours if necessary.

Cattle: Administer intravenously or intramuscularly at a dose of 0.5 mg per lb of body weight (2.5 mL for each 100 lbs of body weight). This dose may be repeated in 6-12 hours if necessary. The intravenous route of administration may provide a more rapid onset of action. Use aseptic technique to administer RE-COVR™ (tripelennamine hydrochloride injection).

Warm the solution to near body temperature prior to administration. Intramuscular injection should be made into the heavy musculature of the hind leg or cervical area.

While venomous snake bites have been treated with antihistaminic drugs, other conjunctive therapy is required because of toxic reactions associated with the protein complex of venom.

Do not puncture the stopper more than 30 times, use within the 24-month product expiry.

STORAGE AND HANDLING:

Store at 20°C to 25°C (68°F - 77°F), excursions permitted between 15°C to 30°C (59°F and 86°F). Keep from freezing. Protect from light.

Manufactured For:

KineticVet, PO Box 12388, Lexington, KY 40538

Made in USA

www.KineticVet.com

TAKE TIME OBSERVE LABEL DIRECTIONS

Before using this drug, read package onsert for full prescribing information.

WITHDRAWAL PERIODS AND RESIDUE WARNINGS:

Cattle: Milk taken during treatment and for 24 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 4 days following the last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdrawal period has not been established for this product in pre-ruminating calves.

ANIMAL SAFETY WARNINGS:

Administration of tripelennamine hydrochloride may give rise to excitement, ataxia, and convulsions.

Central nervous system stimulation in the form of hyperexcitability, nervousness, and muscle tremors lasting up to 20 minutes have been noted in horses following administration.

Depression of the central nervous system and incoordination may occur when the drug is used at therapeutic dose levels. Disturbances in gastrointestinal function may occur in some instances.

OTHER WARNINGS:

Horses - Do not use in horses intended for human consumption.

USER SAFETY WARNINGS:

Not for use in humans. Keep out of reach of children. To obtain a Safety Data Sheet, contact KineticVet at 1-877-786-9882 or www.KineticVet.com.

ACTIVE INGREDIENTS:

Each mL contains 20 mg of tripelennamine hydrochloride USP per mL of aqueous solution.

INACTIVE INGREDIENTS:

Sodium hydroxide may be added to adjust pH.

CONTACT INFORMATION:

Contact KineticVet at (877) 786-9882 or www.KineticVet.com. To report suspected adverse drug experiences, contact KineticVet at (877) 786-9882. For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

HOW SUPPLIED:

100 mL, 250 mL and 500 mL multiple dose vials.

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Manufactured For:

KineticVet I PO Box 12388 I Lexington, KY 40583

Made in USA

www.KineticVet.com

TAKE TIME  OBSERVE LABEL DIRECTIONS

019
T-7476-05
Revision Date: 11-21

RE-COVR™

(tripelennamine hydrochloride injection)

20 mg per mL

Antihistamine

Horses - For intramuscular injection only

Cattle - For intravenous or intramuscular injection

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

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WARNINGS AND PRECAUTIONS:

Withdrawal Periods and Residue Warnings: Cattle: Milk taken during treatment and for 24 hours after the last treatment must not be used for human consumption. Cattle must not be slaughtered for human consumption within 4 days following the last treatment with this drug product. Not for use in beef calves less than 2 months of age, dairy calves, and veal calves. A withdraw period has not been established in the pre-ruminating calves.

NDC 51031-025-25

RE-COVR™ (tripelennamine hydrochloride injection)

20 mg per mL

Antihistamine

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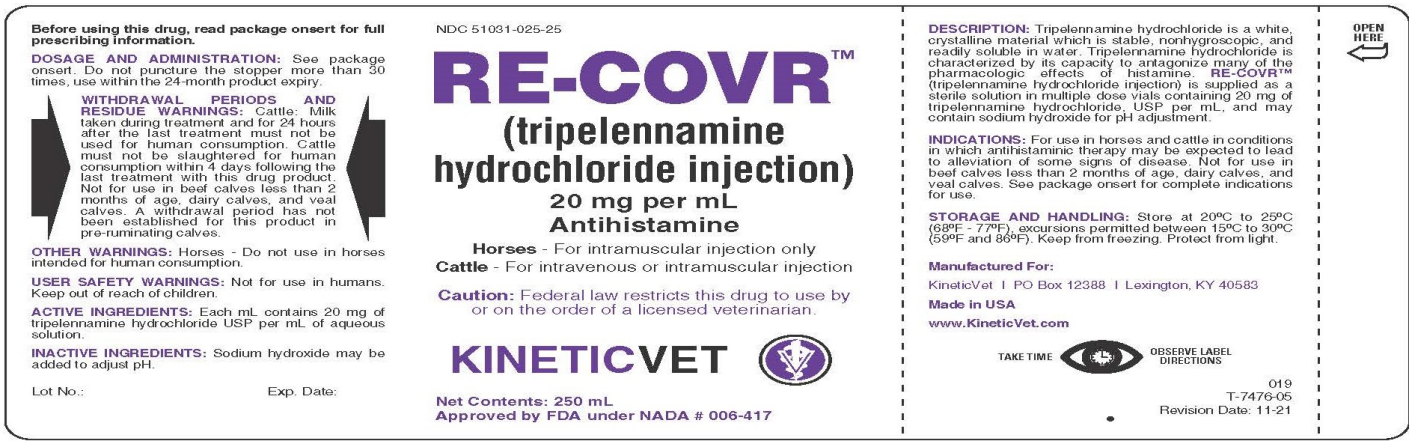
KINETICVET

Net Contents: 250 mL

Approved by FDA under NADA # 006-417



RE-COVR

tripelennamine hydrochloride injection

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:51031-025
Route of Administration	INTRAMUSCULAR, INTRAVENOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRIPELENNAMINE HYDROCHLORIDE (UNII: FWV8GJ56ZN) (TRIPELENNAMINE - UNII:3C5ORO99TY)	TRIPELENNAMINE	20 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51031-025-25	250 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA006417	02/24/2022	

Labeler - Kinetic Technologies, LLC (164935731)