medical attention if irritation develops. In cases of accidental eye exposure, flush with copious amounts of water for at least 15 minutes and get medical attention if irritation develops.

PRECAUTIONS: Intra-thoracic or intra-abdominal injection should be avoided. The user of TREXONIL™ should be proficient in appropriate procedures necessary to handle problems resulting from animals being in lateral or dorsal recumbency for extended periods of time. Users should also have necessary equipment, supplies and experienced personnel to handle such situations that may occur during or following immobilization and reversal procedures to minimize possible injury to the animal or personnel.

Side effects associated with thiafentanil oxalate administration, such as muscle tremors or heavy panting may not immediately abate upon administration of TREXONIL™.

Animals should, if possible, be monitored until any side effects associated with thiafentanil oxalate administration subside.

ADVERSE REACTIONS: Doses of up to 1600 mg of TREXONIL have been administered to elk with no adverse reactions reported (NADA 141-074 Freedom of Information Summary).

STORAGE: Protect from light. Store at controlled room temperature 15-30°C (59°- 86°F) .

HOW SUPPLIED: TREXONIL™ is supplied in 20 mL multiple use vials.

Manufactured for:

Wildlife Pharmaceuticals, Inc.
1230 West Ash
Windsor, CO 80550

Trexonil™

(naltrexone hydrochloride)

injectable soultion

50 mg/mL

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

NOT APPROVED BY FDA - Legally marketed as an FDA indexed product under MIF 900003. Extra-label use prohibited.

Note - In order to be legally marketed an animal drug product intended for a minor species must be Approved, Conditionally Approved, or Indexed by the FDA. THIS PRODUCT IS INDEXED.

It is a violation of Federal Law to use this product in a manner other than as directed in the labeling. The term "minor species" means animals other than humans that are not major species. "Major species" means cattle, horses, swine, chickens, turkeys, dogs, and cats. As used on this label, a "food-producing minor species" is considered to be a minor species of which some members are bred, cultured, farmed, ranched, hunted, caught, trapped or otherwise harvested for the purpose of having the animals or edible products of the animals commercially distributed for consumption by humans or food-producing animals in the United States.

DESCRIPTION: TREXONIL™ is a sterile injectable solution which contains naltrexone hydrochloride as the active ingredient.

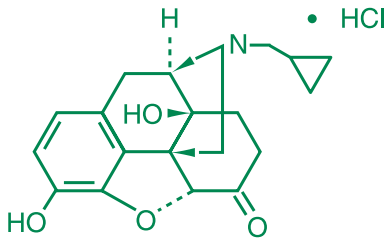
Each mL contains 50 mg naltrexone hydrochloride, 8.6 mg sodium chloride USP, 1.8 mg methylparaben, and 0.2 mg propylparaben NF.

Water for Injection USP.

The pH is adjusted with hydrochloric acid or sodium hydroxide.

Naltrexone hydrochloride is 17-(cyclopropylmethyl)-4, 5-epoxy-3, 14 dihydroxymorphinan-6-one hydrochloride. It has a chemical formula of $C_{20}H_{23}NO_4HCL$ and a molecular weight of 377.9.

Structural Formula:



PHARMACOLOGY: Naltrexone hydrochloride is a cyclopropyl derivative of oxymorphone. It is structurally similar to naloxone and nalorphine and is metabolized by the liver. Studies in rats and mice have indicated that naltrexone has undetectable or minimal narcotic agonist effects. Its relative opiate antagonistic potency is 40 times that of nalorphine and 2-3 times that of naloxone. (Blumberg and Dayton, 1973. Naloxone and Related Compounds in Agonist and Antagonist Actions of Narcotic Analgesic Drugs in: Kosterlitz, H.W., J.O.J. Collier and J. Villarreal, Editors, Proceedings of a British Pharmacology Society Symposium, Scotland, 1971. New York 1073, Macmillan Pub. Co.).

INDICATION: For use as an antagonist of THIANIL (thiafentanil oxalate) immobilization of captive minor species hoofstock, excluding any member of a food-producing minor species such as deer, elk, or bison and any minor species animal that may become eligible for consumption by humans or food-producing animals.

Use only when there is a reasonable certainty that the treated animals will not be consumed by humans or food-producing animals.

DOSAGE AND ADMINISTRATION: Give 10 mg TREXONIL™ for each milligram of thiafentanil oxalate previously administered. The total calculated dose of TREXONIL™ should be administered intramuscularly unless there is a medical or anesthetic emergency requiring immediate reversal, then ¼ of the calculated dose should be administered intravenously and ¾ of the calculated dose should be administered intramuscularly.

Reversal of the effects of thiafentanil oxalate immobilization in minor species hoof stock is usually accomplished 3 to 10 minutes after administration of TREXONIL™. However, in clinical trials, animals have recovered in as little as 2 minutes and occasionally require more than 10 minutes for reversal of the effects of thiafentanil oxalate. Doses lower than the label dose may result in signs of re-narcotization, including open-mouth breathing, hypermetria, ataxia, and subtle changes in behavior and responsiveness.

After administering naltrexone hydrochloride to an animal that has been immobilized with thiafentanil oxalate, it may rise quickly and be fully conscious in as little as 2 minutes. All necessary procedures should have been accomplished and personnel advised that the reversal agent has been administered.

CONTRADICTIONS: The effects of TREXONIL on reproductive performance, pregnancy, and lactation have not been determined.

WARNINGS:

RESIDUE WARNING: FOR USE IN CAPTIVE NON-FOOD-PRODUCING MINOR SPECIES HOOFSTOCK ONLY. NOT FOR USE IN ANY MEMBER OF A NON-FOOD-PRODUCING MINOR SPECIES THAT MAY BECOME ELIGIBLE FOR CONSUMPTION BY HUMANS OR FOOD-PRODUCING ANIMALS. (See definition of food-producing minor species at top of Insert following Caution statements.)

HUMAN WARNINGS: Not for use in humans. Keep out of the reach of children. Care should be taken to avoid accidental human exposure. If accidental self-injection occurs, call a physician immediately. A reaction may occur at the injection site which can be severe. If accidental ingestion occurs, contact a physician. Do not induce vomiting unless directed to do so by medical personnel. Avoid direct contact with skin and eyes. In cases of accidental skin exposure, wash area with soap and water and get