Thianil

(thiafentanil oxalate)

injectable solution

10 mg/mL

CII

For intramuscular injection in captive non-food-producing minor species hoof stock only.

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

NOT APPROVED BY FDA – Legally marked as an FDA Indexed Product under MIF 900 000. 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.

Do not use this product without adequate amounts of reversal agent available.

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.

HUMAN WARNINGS:

Not for use in humans. Keep out of the reach of children. THIANIL contains thiafentanil, a high concentration (10 mg/mL) opioid agonist and Schedule II controlled substance. THIANIL should be handled with extreme caution to avoid accidental exposure.

If accidental self-injection or ingestion occurs, seek immediate medical treatment and provide physician with the vial or package insert/product information. Symptoms of toxicity include dizziness, nausea, and constriction of pupils (pinpoint) followed by respiratory depression, lowered blood pressure, cyanosis, and in extreme cases, loss of consciousness and cardiac arrest. If necessary, apply CPR until medical help arrives.

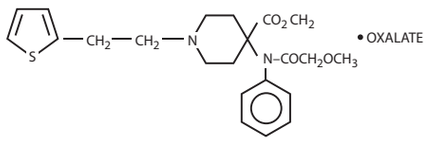
The antidote for human exposure to THIANIL is an opioid antagonist such as naltrexone or naloxone.

If accidental skin exposure occurs, wash area with copious amounts of water and contact a physician. If accidental eye exposure occurs, flush with copious amounts of water for 15 minutes and contact a physician.

Because of the potential for adverse reactions associated with accidental exposure, THIANIL should only be administered by individuals experienced in handling immobilization agents in zoos, exotic animal and wildlife practices, wildlife management programs, and biological research. It is advisable only to handle THIANIL when accompanied by another person. Wear gloves and eye protection when handling THIANIL. The handler should be paired with a second person also knowledgeable about the hazards of working with potent opioids. All personnel involved in an immobilization should be informed that potent opioids are being utilized. Needles and syringes should be secured and safely disposed of as a biohazard following use.

DESCRIPTION: Thiafentanil oxalate is 4-(Methoxycarbonyl)-4-(N-phenylmethoxy-acetamido)-1-[2-(2-thienyl)ethyl]piperidinium oxalate. Its molecular formula is $C_{24}H_{30}N_2O_2S$. Its molecular mass is 506.57. Each mL of THIANIL contains 10mg thiafentanil oxalate and 0.1% methylparaben.

Structural Formula:



PHARMACOLOGY: Thiafentanil oxalate has a morphine-like analgesic mode of action and produces rapid immobilization following intramuscular injection.

INDICATION: For immobilization of captive minor species hoof stock, 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 animal will not be consumed by humans or food-producing animals.

DOSAGE AND ADMINISTRATION: Total doses used in captive minor species hoof stock to date have ranged from 1 mg (Impala) to 15mg (African elephant). Immobilization is usually achieved in 2 to 10 minutes following administration. The most effective dose rate will vary due to the conditions of use. The lower end of the dose range is suggested for those animals of quiet temperament, under confinement, that have not been hotly pursued prior to administration of the drug, or for animals in poor physical condition. The upper end of the dose range is suggested for animals of excitable temperament following extensive pursuit or in instances where an extremely short chase time is desirable. The upper end of the dose range may also be appropriate for animals being pursued by vehicle or aircraft when an extremely quick immobilization time is desired or when individuals are known to be highly excitable. In all instances, all factors including nutritional, reproductive, and health status of an animal as well as environmental conditions (temperature, cover, and terrain) must be evaluated by the user and the best professional judgment used.

Manufactured for

Wildlife Pharmaceuticals, Inc.
1230 W. Ash Street, Suite D, Windsor, CO 80550

DOSE CHART

The following doses are representative of doses used in field trials.

Species	Dose rate of THIANIL In micrograms/kg	*n*	Recommended Total Dose In milligrams
Moose			10mg total dose[2] 10mg[8]
Impala	80.7 µg/kg ED_{90}[1]	44	Male 2mg total dose[3] Female 1mg total dose[3]
African buffalo	17.0 – 37.0µg/kg[5]	9	Field 10mg total dose[3] Boma 5 mg total dose[3]
Eland	37.0 – 110.0µg/kg[5]	8	Male 15mg total dose[3] Female 10mg total dose[3]
Greater kudu	37.0 – 120.0µg/kg[5]	12	Male 15mg total dose[3] Female 8mg total dose[3]
African elephant		9	Male 15mg total dose[3] Female 12mg total dose[3] 15 – 40mg total dose[5]
White rhino		4	Male 5mg total dose[3] Female 4mg total dose[3] 4mg total dose[5]
Waterbuck	34.0 – 43.0µg/kg[5]	10	Male 7mg total dose[3] Female 5mg total dose[3]
Lechwe	47.9µg/kg[6]	5	4mg total dose[3]
Nyala	115.9µg/kg[6]	8	Male 10mg total dose[3] Female 6mg total dose[3]
Waterbuck	24.4µg/kg[6]	9	Male 7mg total dose[3] Female 5mg total dose[3]

[1] Janssen, DL, GE Swan, JP Raath, SW McJames, JL Allen, V de Vos, KE Williams, JM Anderson, and TH Stanley. 1993. Immobilization and physiologic effects of the narcotic A-3080 in impala *(Aepyceros melampus)*. J. Zoo Wildl. Med., 24: 11-18.

[2] Kreeger, TJ and JM Arnemo. 2007. Handbook of Wildlife Chemical Immobilization, 3rd ed. For North and South American orders: tkreeger@starband.net or Amazon.com.

[3] Lance, WR. 2008 Attachment C; Recommended Dosages for Adult Animals South Africa and North America. Wildlife Pharmaceuticals, Inc., Fort Collins, CO 80524. pp. 9-10.

[4] McJames, SW, IL Smith, TH Stanley, and G Painter. 1993. Elk immobilization with potent opioids: A3080 vs. carfentanil. Proc. Conf. Amer. Assoc. Zoo Vet., Saint Louis, Missouri. pp. 418-419.

[5] Raath, JP. 2005 Clinical Expert Report First Study. pp. 1-11.

[6] Raath, JP. 2005 Clinical Expert Report Second Study. pp. 11-22.

[7] Stanley, TH, SW McJames, J Kimball, JD Port, and NL Pace. 1988. Immobilization of elk with A-3080. J. Wildl Mgmt. pp. 577-581.

[8] Stanley, TH, SW McJames, and J Kimball. 1989. Chemical immobilization for the capture and transportation of big game. Proc. Conf. Amer. Assoc. Zoo Vet. Greensboro, North Carolina. pp. 13-14.

Inject dose deep into a large muscle mass of the neck, shoulder, back, or hindquarter. Intra-thoracic, intra-abdominal, or subcutaneous injection is to be avoided. To ensure proper dosage for animals weighing less than 50 kg, remove the calculated dose of THIANIL from the vial with a tuberculin syringe. Dilute appropriate volume with sterile water for injection prior to administration. Operator should use safe technique by working in pairs, wearing disposable latex gloves, and wearing eye protection. Used syringes should be secured and disposed of in an appropriate biohazard container.

ANTIDOTE: TREXONIL™ (naltrexone hydrochloride) is the recommended antidote and rapidly reverses the effects of THIANIL. Administer 10 mg TREXONIL™ for each milligram of THIANIL. The total calculated dose of TREXONIL should be administered intramuscular 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. The entire dose can be safely delivered intravenously but the operator should be prepared for occasional extrapyramidal activity and signs, and/or very rapid return to consciousness and mobility. Reversal of effects of THIANIL are usually observed in 2 to 10 minutes, with differences resulting from whether reversal is performed by intramuscular injection, split between intravenous injection and intramuscular injection, or completely delivered by intravenous injection.

CONTRAINDICATIONS: THIANIL is not for use in minor species hoof stock in the family Equidae. Do not use thiafentanil oxalate in animals that display clinical signs of disease unless its use is imperative to establish a diagnosis and/or administer therapeutic agents. The effects of thiafentanil oxalate on reproductive performance, pregnancy, and lactation have not been determined. An opioid antagonist should always be drawn up, labeled, and readily accessible prior to drawing up thiafentanil oxalate

WARNINGS: As with other opioids, all species immobilized with THIANIL may show signs of excitement, tachycardia or bradycardia, tachypnea or bradypnea, hypertension or hypotension, depressed respiration, cyanosis, poikilothermia, and reaction to sudden noise. Personnel should be advised of these potential opioid effects and trained to respond appropriately.

PRECAUTIONS: THIAFENTANIL OXALATE SHOULD NEVER BE USED UNLESS AN ADEQUATE AMOUNT OF THE REVERSAL AGENT, TREXONIL™ (naltrexone hydrochloride), IS IMMEDIATELY AVAILABLE. Veterinarians using THIANIL should be familiar with clinical procedures such as measurement of pulse and respiration, oxygen saturation, prevention of aspiration, relief of bloat, obstetrics, control of shock and hemorrhage, recognition for hyperventilation, heat exhaustion, capture myopathy, and the immobilization of fractures, etc. In cases of severe excitement during induction or delayed recovery, continued observation is necessary to correct any of the above situations and to insure the animal does not injure itself.

STORAGE: Store at controlled room temperature (59-86°F) in a facility consistent with appropriate Drug Enforcement Agency regulations regarding Schedule II N (narcotic) Class drugs. Protect from prolonged exposure to excessive heat.

HOW SUPPLIED: THIANIL (thiafentanil oxalate) injectable solution is supplied in a sterile 10 mL multiple use glass vial. Each mL of THIANIL contains 10 mg of thiafentanil and 0.1% methylparaben.