

CAPTIVON 98
(etorphine hydrochloride)
Injectable Solution
9.8 mg/ml

VETERINARY INFORMATION SHEET

**PLEASE READ THIS ENTIRE VETERINARY INFORMATION SHEET
AND THE ENTIRE CAPTIVON 98 PACKAGE INSERT PRIOR TO EACH USE.**

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

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

WARNINGS: SERIOUS OR LIFE-THREATENING RISKS TO HUMANS FROM ACCIDENTAL EXPOSURE TO CAPTIVON 98

CAPTIVON 98 is a high concentration (9.8 mg/mL) opioid agonist and Schedule II controlled substance. CAPTIVON 98 should be handled with extreme caution to avoid accidental exposure.

Accidental Human Exposure:

Accidental exposure of even one dose of CAPTIVON 98, especially in children, can result in a fatal overdose of etorphine. Strict adherence to the recommended handling and disposal instructions is of utmost importance to prevent accidental exposure.

If accidental self-injection or ingestion occurs, seek immediate medical treatment, and provide physician with the vial or package insert/Veterinary Information Sheet. The reversal agent for human exposure to CAPTIVON 98 is an opioid antagonist such as naloxone or naltrexone.

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, provide airway support, and apply CPR until medical help arrives.

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.

Life-Threatening Respiratory Depression in Humans:

Serious, life-threatening, or fatal respiratory depression may occur with accidental exposure to or with misuse or abuse of CAPTIVON 98. Monitor for respiratory depression if human exposure to CAPTIVON 98 occurs. Misuse or abuse of CAPTIVON 98 by swallowing, snorting, or injecting poses a significant risk of overdose and death.

Abuse Potential in Humans:

CAPTIVON 98 contains etorphine, an opioid that exposes humans to risks of misuse, abuse, and addiction, which can lead to overdose and death. Use of CAPTIVON 98 may lead to physical dependence. The risk of abuse by humans should be considered when storing, administering, and disposing of CAPTIVON 98. Persons at increased risk for opioid abuse include those with a personal or family history of substance abuse (including drugs or alcohol) or mental illness (e.g., depression).

Risks From Concurrent Misuse or Abuse with Benzodiazepines or Other CNS Depressants in Humans:

Concurrent misuse or abuse of opioids with benzodiazepines or other central nervous system (CNS) depressants, including alcohol, may result in profound sedation, respiratory depression, coma, and death.

See Human Safety Warnings for detailed information.

HUMAN SAFETY WARNINGS:

Not for use in humans. Keep this and all medications out of reach of children.

Accidental exposure to CAPTIVON 98, especially in children, can result in a fatal overdose.

Human User Safety while handling CAPTIVON 98:

Because of the potential for adverse reactions associated with accidental exposure, CAPTIVON 98 should only be administered by veterinarians in zoo and wildlife practice, or individuals under such veterinary supervision, trained in the handling of potent opioids.

It is advisable to **ONLY** handle CAPTIVON 98 when accompanied by another person. Wear gloves. Do not spray, squirt, or spill the drug when filling the syringes. Wash at once with large volumes of water if CAPTIVON 98 comes in contact with eyes, skin, or mucous membranes.

At least two people in the field team should be able to recognize signs of toxicity if accidental exposure occurs. They should be familiar with emergency cardiopulmonary resuscitation procedures plus have **FIRST AID KITS** containing resuscitation aids available.

Information for Physicians

CAPTIVON 98 is a high concentration opioid agonist. Accidental human exposure may produce severe central nervous system depression resulting in respiratory depression or failure followed by coma and death. Treatment should start immediately by administering an appropriate opiate antagonist, providing airway support, and cardiopulmonary resuscitation techniques.

(See reverse side for animal use information).

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(See reverse side for Human Safety Warnings.)

INDICATION:

For immobilization and anesthesia of zoo animals, captive wildlife, and free-ranging wildlife species not intended for use as food.

Use only when there is a reasonable certainty that the treated animal will not be consumed by humans or food-producing animals (see CAPTIVON 98 package insert for details).

DOSING AND ADMINISTRATION:

See CAPTIVON 98 package insert for dosing table. Note that dosing of CAPTIVON 98 is provided in **micrograms/kg** (µg/kg) and/or total **mg** of CAPTIVON 98.

For animal reversal, see ANALGESIC ANTAGONIST FOR ANIMALS section of the CAPTIVON 98 package insert.

CONTRAINDICATIONS:

Do not use CAPTIVON 98 in domestic animals.

Do not use CAPTIVON 98 in feline species.

Do not use CAPTIVON 98 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 CAPTIVON 98 on reproductive performance, pregnancy, and lactation have not been determined.

Do not use CAPTIVON 98 in domestic food-producing animals.

Do not use CAPTIVON 98 thirty (30) days before, or during, the hunting season in free-ranging wild animals that might be used for food. Carcasses of animals treated with CAPTIVON 98 are not to be used for human consumption.

ANIMAL SAFETY WARNINGS:

AN OPIOID ANTAGONIST SUCH AS NALTREXONE HYDROCHLORIDE SHOULD ALWAYS BE DRAWN UP, LABELED, AND READILY ACCESSIBLE TO BE USED AS AN ANIMAL REVERSAL AGENT PRIOR TO DRAWING UP CAPTIVON 98. See CAPTIVON 98 package insert for directions.

All species immobilized with CAPTIVON 98 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 (see CAPTIVON 98 package insert).

CONTACT INFORMATION AND ADVERSE EVENT REPORTING:

To report suspected adverse drug experiences (ADEs) or to obtain additional information about this product, contact:

Clovis-Davis Pharmaceuticals, LLC
1520 South Lapeer Rd, Suite 120
Lake Orion, Michigan 48360
Tel (toll-free): 1-833-878-0060
Email: safety@clovisdavis.com

Adverse events may also be reported to the U.S. Food and Drug Administration (FDA) at 1-888-FDA-VETS (1-888-332-8387) or via <https://www.fda.gov/reportanimalae>

STORAGE:

CAPTIVON 98 is a Schedule II opioid. Store in a locked cabinet at or below 77 °F (25 °C) according to federal and state-controlled substance requirements/guidelines. Once the vial has been pierced, the contents must be used within two weeks. Protect from light and prolonged exposure to excessive heat. Any unused or expired vials must be destroyed by a reverse distributor. For further information, contact your local DEA field office or email Wildlife Pharmaceuticals (Pty) Ltd: pharmacist@wildpharm.co.za.

CAPTIVON 98 (etorphine hydrochloride) is not FDA approved. Due to a shortage of etorphine hydrochloride in the USA, FDA is allowing temporary use of this South African product in the US. CAPTIVON 98 is authorized for marketing in South Africa for the immobilization and anesthesia of zoo animals, captive wildlife, and free-ranging wildlife species not intended for use as food.

NDC NO. 86204-098-05



Manufactured by:
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