

CAPTIVON 98- etorphine hcl injection, solution

Clovis-Davis Pharmaceuticals LLC

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.

Captivon 98

PROPRIETARY NAME AND DOSAGE FORM

CAPTIVON 98 INJECTION

COMPOSITION

Each ml contains: Etorphine hydrochloride 9.8 mg
Preservative: Chlorocresol 0.1 % *m/v*

CATEGORY AND CLASS OF MEDICINE

C 1.3.1 Opioid agonist

PHARMACOLOGICAL ACTION

Etorphine is a highly potent, semi-synthetic opioid derivative of oripavine and is classified as a pure agonist. It acts stereospecifically on μ -, δ - and κ -opioid receptors, inducing catatonia associated with analgesia at low doses.

PHARMACOKINETIC PROPERTIES AND PHARMACODYNAMIC PROPERTIES

Following intramuscular administration of optimal doses, onset of action in most wildlife species is observed within 2–8 minutes with the full effect reached in 15–30 minutes. In rodents, the analgesic effect peaks sharply at 15 minutes with a duration of action of approximately 50 minutes. In elephants, peak serum concentration is reached 30 minutes after intramuscular injection with a half-life of 66 minutes and clearance of 13.6 ml/min/kg.

Etorphine is primarily eliminated in the bile and excreted in the faeces with some excretion occurring in the urine. Full recovery from the effects of etorphine can take up to 7-8 hours if an opioid antagonist is not administered. Re-cycling of etorphine via enterohepatic circulation or redistribution from adipose depots may lead to re-narcotisation of the animal.

INDICATIONS

CAPTIVON 98 is indicated for immobilisation and anaesthesia of zoo animals, captive

wildlife, and free-ranging wildlife species not intended for use as food.

CONTRAINDICATIONS

Do not use CAPTIVON 98 in domestic animals and wild felids.

Do not use carcasses of animals treated with etorphine for human consumption.

CAPTIVON 98 residue studies have not been conducted in wildlife animals and consequently, human and predator consumption of carcasses from animals treated with CAPTIVON 98 is not advisable.

DOSAGE AND DIRECTIONS FOR USE IN ANIMALS

CAPTIVON 98 (etorphine hydrochloride) dosing is dependent on species, body mass and the condition of the wildlife animal being treated, and doses should be adjusted accordingly. Administration by intravenous or intramuscular injection is recommended. Refer to the table for CAPTIVON 98 dosing.

ANALGESIC ANTAGONIST FOR ANIMALS

The effects of CAPTIVON 98 may be reversed by administering naltrexone hydrochloride 50 mg/mL at a ratio of 20 mg of naltrexone hydrochloride for every 1 mg of CAPTIVON 98 used.

SIDE EFFECTS AND SPECIAL PRECAUTIONS FOR USE IN ANIMALS

The most serious adverse effect following CAPTIVON 98 administration is respiratory depression, usually observed within the first five minutes after administration. In cases of severe respiratory depression, CAPTIVON 98 should be reversed as soon as possible, and animals should not remain immobilised for longer than necessary to avoid complications.

The use of CAPTIVON 98 in elderly, diseased, emaciated and highly stressed animals carries a greater degree of risk and precautionary measures should be taken, including maintenance of airways and prevention of hyperthermia.

Equids and rhino:

- CAPTIVON 98 may result in a dramatic rise in blood pressure, tachycardia, hyperpyrexia and pronounced muscle tremors.
- Administration in rhino may lead to hypoventilation, hypoxaemia and metabolic acidosis.

Ungulates

- Significant hypertension due to an increase in total peripheral resistance, and moderate to severe bradycardia has been reported in ungulate species.
- Excitement, increased muscle tone and resulting hyperthermia is particularly common in ungulates.
- Passive regurgitation of rumen contents is common, and ruminants should be kept in

sternal recumbency with heads lifted and tilted downwards to prevent aspiration pneumonia.

- Under-dosing may cause hyper-excitability, hyperventilation and severe alkalosis. The safety of CAPTIVON 98 in pregnant and lactating wildlife animals has not been established. There is a risk of respiratory depression in the newborn if CAPTIVON 98 is given to a parturient animal. Rodent studies have shown that etorphine readily crosses the placental barrier. Etorphine administered in pregnant rats results in respiratory depression in the mother and depressed oxygen uptake in the newborn rats that is directly proportional to the maternal dose.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT FOR ANIMALS

CAPTIVON 98 toxicity in wildlife animals results in respiratory depression and cardiac suppression. Rhinos are particularly sensitive to CAPTIVON 98.

An overdose can be treated with naltrexone hydrochloride and with analeptics such as doxapram hydrochloride. Oxygen supplementation is recommended in cases of severe respiratory depression. Butorphanol tartrate may be used to partially reverse respiratory depression and to lighten the plane of anaesthesia of large species such as rhino. In the latter case, the animals may be walked under sedation onto vehicles for transport.

HUMAN SAFETY WARNINGS

Accidental exposure to CAPTIVON 98 could have serious effects on humans due to the high concentration of the medicine.

- The lethal CAPTIVON 98 dose in humans is estimated to be between 30-120 µg.

The following precautions should be taken by veterinarians when using CAPTIVON 98:

- Do not work with CAPTIVON 98 unaccompanied.
- Ensure that the antidote (naloxone), and a needle and syringe for administration of the antidote are readily available.
- An assistant capable of administering the antidote to humans should always be present and should be fully briefed on the procedure to follow in the event of accidental exposure to CAPTIVON 98.
- Wear gloves when handling CAPTIVON 98.
- Eye protection should be utilised if there is a risk of CAPTIVON 98 splashing into the eyes.
- Ensure water or an appropriate irrigation solution is available to treat accidental exposure of the skin or eyes.
- CAPTIVON 98 should not be used in blowpipes or similar devices where the medicine solution is pressurised.
- Accidental jabbing with a needle containing CAPTIVON 98 could have serious effects. Once the required dose of CAPTIVON 98 has been withdrawn from the vial, the needle should be immediately discarded into a closed container or sharps bin.

SYMPTOMS OF TOXICITY IN HUMANS

- Symptoms of toxicity in humans include dizziness, nausea, pinpoint pupils, respiratory depression, hypotension, loss of consciousness and cardiac arrest.
- In the event of accidental topical exposure of the skin or eyes, wash the affected area immediately with copious amounts of water to prevent absorption. Monitor for symptoms of toxicity.
- Should accidental injection occur, seek medical attention immediately.

BEFORE CALLING FOR MEDICAL ASSISTANCE, INJECT THE ANTIDOTE.

ADMINISTRATION OF THE ANTIDOTE FOR HUMANS

- Inject 0.8-1.2 mg naloxone preferably IV or alternatively IM and repeat at 2-3 minute intervals until symptoms are reversed. Monitor airway and ventilation and initiate CPR as necessary until medical help arrives.

IDENTIFICATION

A clear, colourless solution for injection.

PRESENTATION

CAPTIVON 98 is supplied in an amber 10 mL glass vial filled to 5 mL.

STORAGE INSTRUCTIONS

Store at or below 25 °C. Protect from light.

Once the rubber stopper has been pierced, the contents of the vial should be used within two weeks.

KEEP OUT OF REACH OF CHILDREN AND UNINFORMED PERSONS.

REGISTRATION NUMBER

93/1.3.1/10

NAME AND BUSINESS ADDRESS OF HOLDER OF CERTIFICATE OF REGISTRATION

Wildlife Pharmaceuticals (Pty) Ltd
38 Wilken Street
Rocky Drift
White River 1240
South Africa

Dosage and Administration

Recommended CAPTIVON 98 (etorphine hydrochloride) doses alone or in combination with other drugs NOTE: Doses are provided in total mg, mg/kg and/or ug/kg. (from

Species	Weight (kg)	CAPTIVON 98 dose ϕ ¥(INTRAMUSCULAR ADMINISTRATION)
		10-12 mg CAPTIVON 98 + 40-60 mg azaperone 14-20 mg CAPTIVON 98 + 40-60 mg azaperone
African elephant (<i>Loxodonta africana</i>)	Adult female	
	Adult male	
	Sub-adult (2 m shoulder height)	9 mg CAPTIVON 98 + 40 mg azaperone
	Sub-adult (1.8-2 m shoulder height)	6 mg CAPTIVON 98 + 40 mg azaperone
	Sub-adult (1.5-1.8 m shoulder height)	3-4 mg CAPTIVON 98 + 40 mg azaperone
Arabian oryx (<i>Oryx leucoryx</i>)	Sub-adult (<2 m shoulder height)	2 mg CAPTIVON 98 + 40 mg azaperone
	80-120	50 µg/kg CAPTIVON 98 + 5 µg/kg medetomidine
Black rhino (<i>Diceros bicornis</i>)	600-1400	2-4 µg/kg CAPTIVON 98* + 40-60 mg azaperone
	60	90 µg/kg CAPTIVON 98
Blesbok (<i>Damaliscus pygargus phillipsi</i>)	60	50 µg/kg CAPTIVON 98 + 0.35-0.6 mg/kg azaperone
Blue wildebeest (<i>Connochaetes taurinus</i>)	180-270	10-20 µg/kg CAPTIVON 98 + 0.1-0.2 mg/kg azaperone
Bushbuck (<i>Tragelaphus scriptus</i>)	30-50	40-50 µg/kg CAPTIVON 98 + 1.2 mg/kg azaperone
	750-850	10-15 µg/kg CAPTIVON 98 + 0.1-0.15 mg/kg azaperone
Buffalo (<i>Syncerus caffer</i>)	250-460	10-15 µg/kg CAPTIVON 98 + 0.15 mg/kg midazolam
	200-280	20 µg/kg CAPTIVON 98 + 0.2-0.3 mg/kg azaperone
Cape mountain zebra (<i>Equus zebra zebra</i>)	200-280	20-30 µg/kg CAPTIVON 98 + 20-30 µg/kg medetomidine
Gemsbok (<i>Oryx gazella</i>)	200-250	20-30 µg/kg CAPTIVON 98 + 0.4 mg/kg azaperone
	200-250	10-20 µg/kg CAPTIVON 98 OR
Giraffe (<i>Giraffa camelopardalis</i>)	700-1400	10-20 µg/kg CAPTIVON 98 + 0.7 mg/kg azaperone
	35-40	90 µg/kg CAPTIVON 98
Impala (<i>Aepyceros melampus</i>)	30-50	30-60 µg/kg CAPTIVON 98 + 0.4-0.6 mg/kg azaperone
	120-260	40-50 µg/kg CAPTIVON 98 + 0.4-0.8 mg/kg azaperone
Kudu (<i>Tragelaphus strepsiceros</i>)	120-260	60 µg/kg CAPTIVON 98 + 0.04-0.04 mg/kg medetomidine
	120-260	60-70 µg/kg CAPTIVON 98 + 0.6-0.8 mg/kg azaperone
Lechwe (<i>Kobus leche</i>)	60-110	

Plains zebra (<i>Equus quagga</i>)	290-340	10-20 µg/kg CAPTIVON 98 + 0.1 mg/kg azaperone
Red hartebeest (<i>Alcelaphus caama</i>)	120-150	40 µg/kg CAPTIVON 98 + 0.5 mg/kg azaperone
Reedbuck (<i>Redunca arundinum</i>)	50-70	40-50 µg/kg CAPTIVON 98 + 0.6-0.8 mg/kg azaperone
Roan (<i>Hippotragus equinus</i>)	220-300	20-30 µg/kg CAPTIVON 98 + 0.15-0.2 mg/kg azaperone
Springbok (<i>Antidorcas marsupialis</i>)	35-40	20-30 µg/kg CAPTIVON 98 + 0.3-0.5 mg/kg azaperone
Steenbok (<i>Raphicerus campestris</i>)	8-11	40-50 µg/kg CAPTIVON 98 + 1.8-2.5 mg/kg azaperone
Tsessebe (<i>Damaliscus lunatus</i>)	120-140	30 µg/kg CAPTIVON 98 + 0.3-0.4 mg/kg azaperone
White rhino (<i>Ceratotherium simum</i>)	1000-1500	2-2.5 CAPTIVON 98 + 0.03-0.04 mg/kg azaperone
	300-2300	1-3 CAPTIVON 98* + 0.01-0.03 mg/kg midazolam

Φ Higher dose range recommended for nervous/excited animals or immobilisation where a short induction period is needed. Lower dose range recommended for weak/sick/debilitated/ tame animals or where longer induction times are allowable and/or for animals in captivity or where movement is restricted e.g. zoos.

¥ The level of opioid anaesthesia can be decreased to the desired level by concurrent intravenous administration of butorphanol tartrate.

* The higher dosage range is recommended for smaller animal.

Recommended CAPTIVON 98 (etorphine hydrochloride) doses alone or in combination with other drugs NOTE: Doses are provided in total mg, mg/kg and/or ug/kg. (from literature)		
Species	Weight (kg)	CAPTIVON 98 dose ^{Φ*} (INTRAMUSCULAR ADMINISTRATION)
African elephant (<i>Loxodonta africana</i>)	Adult female	10-12 mg CAPTIVON 98 + 40-60 mg azaperone
	Adult male	14-20 mg CAPTIVON 98 + 40-60 mg azaperone
	Sub-adult (2 m shoulder height)	9 mg CAPTIVON 98 + 40 mg azaperone
	Sub-adult (1.8-2 m shoulder height)	6 mg CAPTIVON 98 + 40 mg azaperone
	Sub-adult (1.5-1.8 m shoulder height)	3-4 mg CAPTIVON 98 + 40 mg azaperone
	Sub-adult (<2 m shoulder height)	2 mg CAPTIVON 98 + 40 mg azaperone
Arabian oryx (<i>Oryx leucoryx</i>)	80-120	50 µg/kg CAPTIVON 98 + 5 µg/kg medetomidine
Black rhino (<i>Diceros bicornis</i>)	600-1400	2-4 µg/kg CAPTIVON 98* + 40-60 mg azaperone
Blesbok (<i>Damaliscus pygargus phillipsi</i>)	60	90 µg/kg CAPTIVON 98
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* The higher dosage range is recommended for smaller animal.

VETERINARY INFORMATION SHEET

CII

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)

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 ($\mu\text{g/kg}$) 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:

Clovis Davis Pharmaceuticals, LLC
2518 Burnsed Blvd. Ste. 610. The Villages, FL 32163
(313) 466 6469
info@clovisdavis.com

To report suspected adverse drug experiences, contact Wildlife Pharmaceuticals (Pty) Ltd: pharmacist@wildpharm.co.za.

For additional information about reporting adverse drug experiences for animal drugs, contact FDA at 1-888-FDA-VETS (1-888-332-8387) or <http://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 US, 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

Wildlife Pharmaceuticals (Pty) Ltd
38 Wilken Street
Rocky Drift
White River 1240, South Africa
+27 13 751 2328

DISTRIBUTED BY
Clovis-Davis Pharmaceuticals, LLC

1520 South Lapeer Rd, Suite 120
Lake Orion, Michigan 48360
833-878-0060

VIAL LABEL

CAPTIVON 98

ETORPHINE HCl 9.8 mg/mL

INJECTABLE SOLUTION

CII

IMMOBILIZATION AGENT

FOR IV / IM USE

WARNING: Due to serious human safety and abuse concerns, read the entire Veterinary Information Sheet and Package Insert before using this drug, including the complete Boxed Warning.

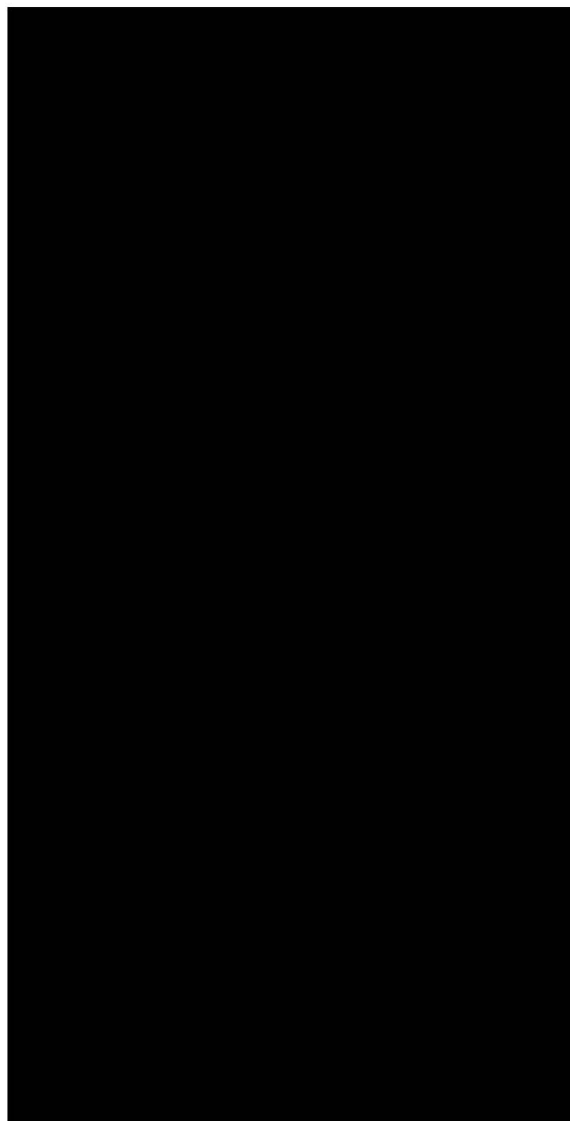
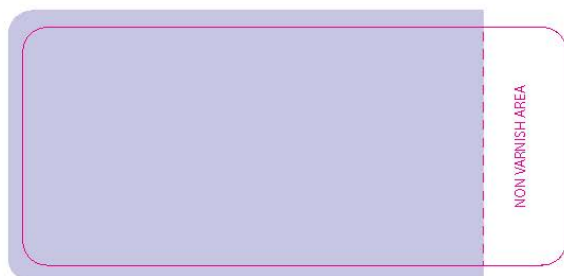
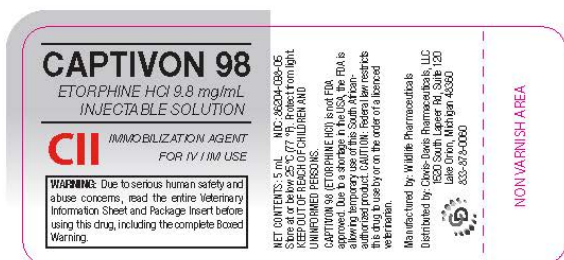
NET CONTENTS: 5 mL NDC: 86204-098-05
Store at or below 25 °C (77 °F). Protect from light.
KEEP OUT OF REACH OF CHILDREN AND
UNINFORMED PERSONS.

CAPTIVON 98 (ETORPHINE HCl) is not FDA approved. Due to a shortage in the USA, the FDA is allowing temporary use of this South African authorized product. **CAUTION:** Federal law restricts this drug to use by or on the order of a licenced veterinarian.

Manufactured by: Wildlife Pharmaceuticals

Distributed by: Clovis-Davis Pharmaceuticals, LLC

1520 South Lapeer Rd, Suite 120 Lake Orion, Michigan 48360
833-878-0060



CARTON

VETERINARY MEDICINE

CAPTIVON 98

ETORPHINE HCl 9.8 mg/mL
INJECTABLE SOLUTION

CII

WARNING: Due to serious human safety and abuse concerns, read the entire Veterinary Information Sheet and Package Insert before using this drug, including the

complete Boxed Warning.

CAPTIVON 98 (ETORPHINE HCl) is not FDA approved. Due to a shortage in the US, the FDA is allowing temporary use of this South African-authorized product.

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

NDC NO. 86204-098-05

Net contents: 5 mL
Immobilization agent for IV / IM
injection in zoo & wildlife species.

Store at or below 25 °C (77 °F).
Protect from light. KEEP OUT OF
REACH OF CHILDREN AND
UNINFORMED PERSONS.

Once the vial is pierced, contents
must be used within two weeks.

Date first opened:

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 handling of potent opioids.

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

Manufactured by:

WILDLIFE PHARMACEUTICALS (Pty)Ltd

38 Wilken Street

Rocky Drift

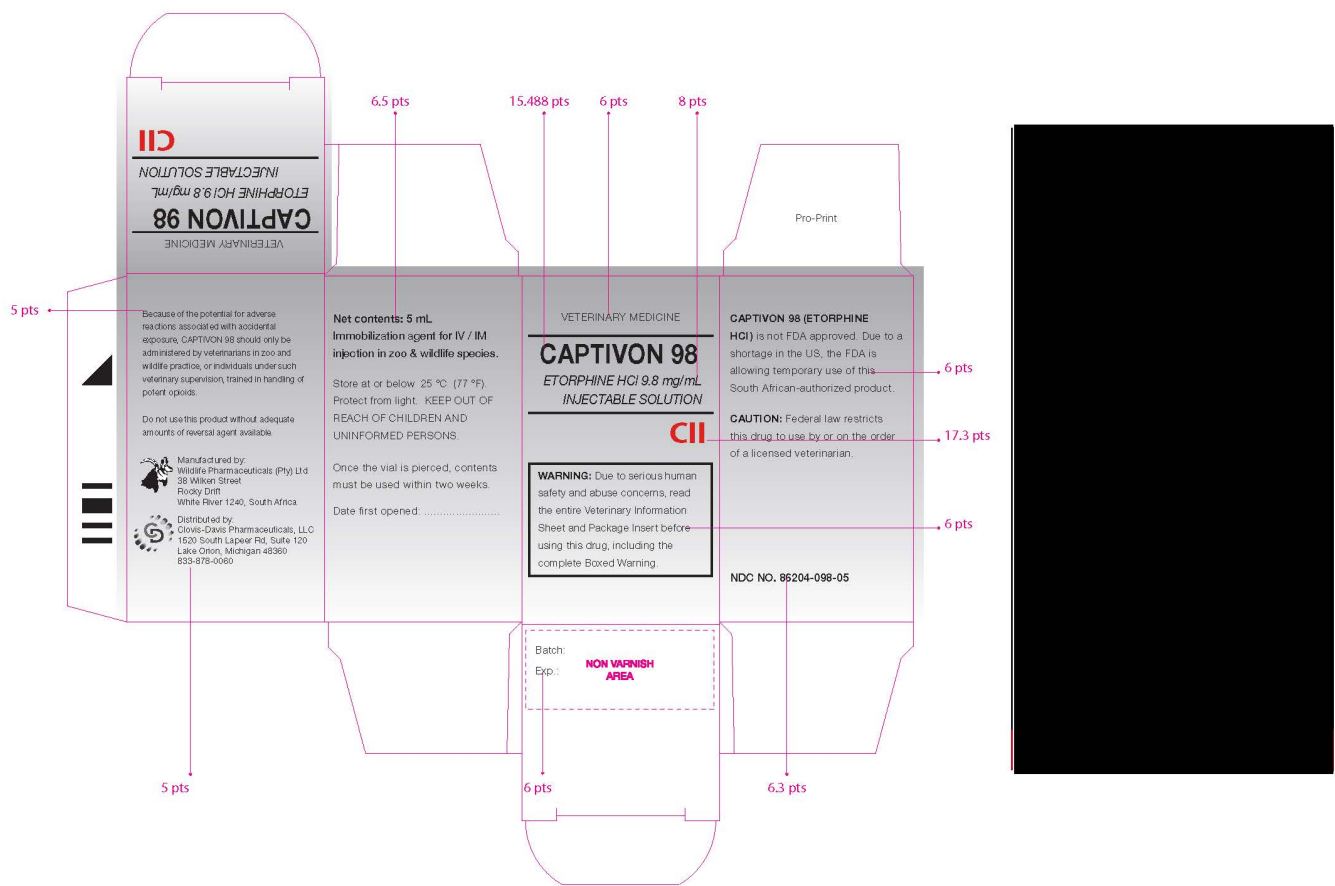
White River 1240, South Africa

Distributed by:

Clovis-Davis Pharmaceuticals, LLC
1520 South Lapeer Rd, Suite 120
Lake Orion, Michigan 48360
833-878-0060

Batch:

Exp.:



CAPTIVON 98

etorphine hcl injection, solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:86204-098
Route of Administration	INTRAMUSCULAR	DEA Schedule	CII

Active Ingredient/Active Moiety		
Ingredient Name	Basis of Strength	Strength
ETORPHINE HYDROCHLORIDE (UNII: 8CBE01N748) (ETORPHINE - UNII:42M2Y6NU9O)	ETORPHINE	9.0 mg in 1 mL

Inactive Ingredients	
Ingredient Name	Strength
Chlorocresol (UNII: 36W53O7109)	

Sodium chloride (UNII: 451W47IQ8X)

WATER (UNII: 059QF0KO0R)

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:86204-098-05	1 in 1 CARTON		
1		5 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
unapproved drug other		12/08/2025	

Labeler - Clovis-Davis Pharmaceuticals LLC (119008775)

Registrant - Wildlife Laboratories Inc (055417281)

Establishment

Name	Address	ID/FEI	Business Operations
Wildlife Pharmaceuticals Pty Ltd		639405794	manufacture, api manufacture

Revised: 12/2025

Clovis-Davis Pharmaceuticals LLC