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Alfaxan® Multidose

IDX

(alfaxalone) 10 mg/mL

For use as an injectable sedative and anesthetic in multiple non food-producing minor species.

10 mL

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

JUROX

NDC 49480-003-01

Before using this drug, read package insert for complete product information.

470795

Distributed by Vedco, Inc.
Marketed by Jurox Inc. Phone 1-844-253-2926.
Legally Marketed – MIF 900-031. Extra-label use is prohibited.
Store at controlled room temperature 20° to 25°C (68° to 77° F) with excursions between 15° and 30°C (59° and 86°F).
Use within 56 days of first puncture.

Use by VFA

Batch Exp. VFA

(IV)

Alfaxan® Multidose

IDX

(alfaxalone) 10 mg/mL

For use as an injectable sedative and anesthetic in multiple non food-producing minor species.

20 mL

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

JUROX

NDC 49480-003-02

Before using this drug, read package insert for complete product information.

470815

Distributed by Vedco, Inc.
Marketed by Jurox Inc. Phone 1-844-253-2926.
Legally Marketed – MIF 900-031. Extra-label use is prohibited.
Store at controlled room temperature 20° to 25°C (68° to 77° F) with excursions between 15° and 30°C (59° and 86°F).
Use within 56 days of first puncture.

Use by VF-A

Batch Exp. VF-A


Alfaxan® Multidose
IDX
(alfaxalone) 10 mg/mL
10 mL
IV
Alfaxan® Multidose
IDX
(alfaxalone) 10 mg/mL
For use as an injectable sedative and anesthetic in multiple non food-producing minor species.
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
10 mL
Jurox
This product is INDEXED - MIF 900-031
NDC 49480-003-01
INDICATIONS:
ALFAXAN MULTIDOSE IDX is indicated for sedation and anesthesia of multiple minor species, excluding any member of a food-producing minor species and any minor species animal that may become eligible for consumption by humans or food-producing animals.
Before using this drug, read package insert for complete product information.
DOSAGE AND ADMINISTRATION:
See package insert.
Store at controlled room temperature 20° to 25°C (68° to 77° F) with excursions between 15° and 30°C (59° and 86°F). Use within 56 days of first puncture.
Use by
VFA
470805
PEMARAPACK
Batch
Exp.
VFA
9 338094 029890
WARNING: For veterinary use only. Keep out of the reach of children. This product is not to be used in animals for use as food for humans or food-producing animals.
First Aid: In the case of accidental human injection, seek medical advice immediately and show the package insert or the label to the physician. If the product comes into contact with the eyes or skin, wash off immediately with water.
LEGAL STATUS—In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Conditionally Approved, or Indexed by the Food and Drug Administration. THIS PRODUCT IS INDEXED—MIF 900-031. Extra-label use is prohibited.
Manufactured in Australia by Jurox Pty Ltd.
Marketed by:
Jurox Inc.
North Kansas City, MO 64116
Phone 1-844-253-2926.
Distributed by:
Vedco, Inc.
St Joseph, MO 64507.


IV
Alfaxan® Multidose
IDX
(alfaxalone) 10 mg/mL
20 mL
IV
Alfaxan® Multidose
IDX
(alfaxalone) 10 mg/mL
For use as an injectable sedative and anesthetic in multiple non food-producing minor species.
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
20 mL
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NDC 49480-003-02
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Use by
VFA
470820
PEMARAPACK
IV
Alfaxan® Multidose
IDX
(alfaxalone) 10 mg/mL
For use as an injectable sedative and anesthetic in multiple non food-producing minor species.
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
20 mL
Jurox
This product is INDEXED - MIF 900-031
Batch
Exp.
VFA
9 338094 029906
WARNING: For veterinary use only. Keep out of the reach of children. This product is not to be used in animals for use as food for humans or food-producing animals.
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10 mL
× 10 vials

Alfaxan® Multidose
IDX
(alfaxalone) 10 mg/mL

IV

Alfaxan® Multidose
IDX
(alfaxalone) 10 mg/mL

IV

10 mL
× 10 vials

Jurox

Before using this drug, read package insert for complete product information.

Store at controlled room temperature
20° to 25°C (68° to 77° F) with excursions between
15° and 30°C (59° and 86°F).
Use within 56 days of first puncture.

Legally Marketed – MIF 900-031. Extra-label use is prohibited.

Manufactured in Australia by Jurox Pty Limited.

Marketed by: Jurox Inc., North Kansas City, MO 64116.
Phone 1-844-253-2926.

Distributed by: Vedco, Inc., St Joseph, MO 64507.

Jurox

NDC 49480-003-01

WARNING: For veterinary use only. Keep out of the reach of children. This product is not to be used in animals for use as food for humans or food producing animals.

First Aid: In the case of accidental human injection, seek medical advice immediately and show the package insert or the label to the physician. If the product comes into contact with the eyes or skin, wash off immediately with water.

The Safety Data Sheet (SDS) contains more detailed occupational safety information.

To report adverse reactions in users or to obtain a copy of the SDS for this product call 1-844-253-2926.

470810

IV

Alfaxan® Multidose

IDX

(alfaxalone) 10 mg/mL

For use as an injectable sedative and anesthetic in multiple non food-producing minor species.

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

10 mL
× 10 vials

10 mL
× 10 vials

Alfaxan® Multidose
IDX
(alfaxalone) 10 mg/mL

IV

20 mL
× 10 vials

Alfaxan® Multidose
IDX
(alfaxalone) 10 mg/mL

IV

20 mL
× 10 vials

Alfaxan® Multidose
IDX
(alfaxalone) 10 mg/mL

IV

Jurox

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15° and 30°C (59° and 86°F).
Use within 56 days of first puncture.

Legally Marketed – MIF 900-031. Extra-label use is prohibited.

Manufactured in Australia by Jurox Pty Limited.

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Phone 1-844-253-2926.

Distributed by: Vedco, Inc., St Joseph, MO 64507.

Jurox

NDC 49480-003-02

WARNING: For veterinary use only. Keep out of the reach of children. This product is not to be used in animals for use as food for humans or food producing animals.

First Aid: In the case of accidental human injection, seek medical advice immediately and show the package insert or the label to the physician. If the product comes into contact with the eyes or skin, wash off immediately with water.

The Safety Data Sheet (SDS) contains more detailed occupational safety information.

To report adverse reactions in users or to obtain a copy of the SDS for this product call 1-844-253-2926.

470825

IV

Alfaxan® Multidose

IDX

(alfaxalone) 10 mg/mL

For use as an injectable sedative and anesthetic in multiple non food-producing minor species.

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

20 mL
× 10 vials

FOR ANIMAL USE ONLY

Alfaxan® Multidose IDX IV

(alfaxalone) 10 mg/mL injectable solution

For use as an injectable sedative and anesthetic in multiple non food-producing minor species.

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

LEGAL STATUS: In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Conditionally Approved, or Indexed by the Food and Drug Administration. THIS PRODUCT IS INDEXED—MIF 900-031. EXTRA-LABEL USE IS PROHIBITED.

This product is not to be used in animals for use as food for humans or food-producing animals.

DESCRIPTION

ALFAXAN MULTIDOSE IDX contains alfaxalone, a neuroactive steroid molecule with properties of a general anesthetic. Alfaxalone is chemically described as 3-α-hydroxy-5-α-pregnane-11, 20-dione, and has a molecular weight of 332.5. The primary mechanism for the anesthetic action of alfaxalone is modulation of neuronal cell membrane chloride ion transport, induced by binding of alfaxalone to GABAA (gamma-aminobutyric acid) cell surface receptors. **This product contains the following preservatives: chlorocresol (0.1% w/v), benzethonium chloride (0.02% w/v) and ethanol (15% w/v).**

INDICATIONS

ALFAXAN MULTIDOSE IDX is indicated as a sedative and anesthetic in multiple minor species*. More specifically, ALFAXAN MULTIDOSE IDX is indicated for the following:

- For sedation and anesthesia in captive reptiles, excluding any food-producing species**
- For sedation and anesthesia in captive amphibians, excluding any food-producing species**
- For sedation and anesthesia in ornamental fish, including species used in research such as the zebra fish
- For sedation and anesthesia in captive species and pet birds in the orders Psittaciformes, Passeriformes, and Columbiformes, excluding any food-producing species**
- For sedation and anesthesia in non-human primates
- For sedation and anesthesia in captive rodents
- For sedation and anesthesia in captive mustelids
- For sedation and anesthesia in captive marsupials
- For induction of anesthesia and immobilization in captive minor species ungulates, excluding any food-producing species**

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

*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.

DOSAGE AND ADMINISTRATION

When administering ALFAXAN MULTIDOSE IDX by intravenous injection administer slowly to effect, titrating administration against the response of the patient. Rapid administration of ALFAXAN MULTIDOSE IDX may be associated with an increased incidence of cardiorespiratory depression or apnea. The use of preanesthetics may reduce the ALFAXAN MULTIDOSE IDX induction dose. The choice and the amount of phenothiazine, alpha$_2$- adrenoreceptor agonist, benzodiazepine or opioid will influence the response of the patient to an induction dose of ALFAXAN MULTIDOSE IDX.

When using ALFAXAN MULTIDOSE IDX, patients should be continuously monitored, and facilities for the maintenance of a patent airway, artificial ventilation, and oxygen supplementation must be immediately available.

ALFAXAN MULTIDOSE IDX contains preservatives. Use within 56 days of first puncture. Any unused ALFAXAN MULTIDOSE IDX remaining after 56 days should be discarded.

The following tables outline the dosage and administration of ALFAXAN MULTIDOSE IDX for the indicated species by major group. The doses are representative of doses published in the literature. Veterinarians are advised to consult the published literature before use of the product (see List of References at end of product insert).

REPTILES

Lizards

Common Name	ALFAXAN MULTIDOSE IDX Dose & Route	Concomitant Drug(s) Dose & Route	Outcome/ Comments	Precautions/ Adverse Reactions	Reference Number
Blotched Bluetongue Lizard	9 mg/kg; IV	None	Ventral coccygeal vein; anesthesia not achieved in all cases		1
Eastern Bluetongue Lizard			Ventral coccygeal vein over 10 sec; anesthesia		1
Coastal Bearded Dragon					1
Inland Bearded Dragon					1
Gippsland Water Dragon					1
Green Iguana	20 mg/kg; IM	None	Anesthesia		2
	5 mg/kg; IM	None	Anesthesia		3
Veiled Chameleon	3 mg/kg; IV	None	Ventral coccygeal vein; anesthesia		4
Leopard Gecko	15 mg/kg; SC	Midazolam 1 mg/kg; SC	Deep sedation		5
	5 mg/kg; IV	None	Anesthesia		6
Perentile Monitor	5 mg/kg; IV	None	Anesthesia		7
Bearded Dragon	5 mg/kg; IV	None	Anesthesia		8
	12 mg/kg; IV	None	Anesthesia		9

Snakes

Common Name	ALFAXAN MULTIDOSE IDX Dose & Route	Concomitant Drug(s) Dose & Route	Outcome/ Comments	Precautions/ Adverse Reactions	Reference Number
Red Bellied Black	9 mg/kg; IV	None	Ventral coccygeal vein; anesthesia		1
Lowland Copperhead					1
Eastern Tiger					1
Coastal Carpet					1
Black Headed					1
Ball Python	20 mg/kg; IM	None	Anesthesia (cranial injection site required)		10

Garter Snake	30 mg/kg; Intracoelomic	None	Loss of righting reflex		11

Turtles and Tortoises

Common Name	ALFAXAN MULTIDOSE IDX Dose & Route	Concomitant Drug(s) Dose & Route	Outcome/ Comments	Precautions/ Adverse Reactions	Reference Number
Red Eared Slider Turtle	5 mg/kg; IV	None	Anesthesia		12
	10-20 mg/kg; IM	None	Lower environmental temperatures and or body temperature prolonged anesthesia		13
Loggerhead Sea Turtle	3, 5 and 10 mg/kg; IV	None	Anesthesia	10 mg/kg dose produced apnea	14
Hartmann's Tortoise	5 mg/kg; IV	None	Anesthesia		12
Spur-Thighed Tortoise					12
Marginated Tortoise					12
Russian Tortoise	5 mg/kg; IV	None	Anesthesia		12
	10 mg/kg; IM	Medetomidine 0.05 mg/kg; IM	Moderate/deep sedation; minimal analgesia	Bradycardia was observed with this combination of drugs	15
	20 mg/kg; IM	Medetomidine 0.1 mg/kg; IM	Deep sedation/anesthesia; variable analgesia		
Red Footed Tortoise	10 mg/kg; IM	Midazolam 1 mg/kg and Hydromorphone 0.5 mg/kg; IM (front legs)	Anesthesia		16
Pond Sliders	10 mg/kg; IV	None	Via subcarapacial vein; Anesthesia		17
Spur-Thighed Tortoise	10 mg/kg; IV	Morphine 1.5 mg/kg and Meloxicam 0.2 mg/kg; SC	Via jugular vein; Anesthesia		18

AMPHIBIANS

Common Name	ALFAXAN MULTIDOSE IDX Dose & Route	Concomitant Drug(s) Dose & Route	Outcome/ Comments	Precautions/ Adverse Reactions	Reference Number
Oriental Fire Bellied Toad	30 mg/L H_2O*; immersion	Butorphanol 25 mg/L H_2O*; immersion (butorphanol combined with ALFAXAN MULTIDOSE IDX in same bath)	Surgical anesthesia was observed in both treatment groups. The baths were adjusted to pH 7±0.2 with sodium bicarbonate, 8.4%. One third of the toad's surface area was immersed to avoid drowning.		19
	30 mg/L H_2O*; immersion	Morphine 50 mg/L H_2O*; immersion (morphine combined with ALFAXAN MULTIDOSE IDX in same bath)			
Australian Frog	30 mg/kg; IM	None	Anesthesia		20

Axolotl	5 mg/L H_2O*; first immersion then continuous irrigation of the gills and skin after the axolotl was removed from the bath	None	The anesthetic bath was prepared to pH 6.5. Additional 30 µL drops of stock ALFAXAN MULTIDOSE IDX were applied to gills when required. Mild sedation was produced with initial immersion and anesthesia produced with subsequent drops.		21

*Anesthetic baths were prepared using dechlorinated mineral water at room temperature

FISH

Common Name	ALFAXAN MULTIDOSE IDX Dose & Route	Concomitant Drug(s) Dose & Route	Outcome/ Comments	Precautions/ Adverse Reactions	Reference Number
Goldfish	0.5, 2, 5 & 7.5 mg/L H_2O^; immersion	None	Sedation at 0.5 and 2 mg/L. Anesthesia at 5 and 7.5 mg/L		22
	5 mg/L H_2O; immersion followed by continuous gill irrigation with 5 mg/L H_2O	None	Anesthesia		23
Koi	10 mg/L H_2O#; immersion followed by continuous gill irrigation with 1 or 2.5 mg/L H_2O	None	All fish anesthetized. Opercular movement observed in 4 of 6 fish at 2.5 mg/L H_2O		24
Oscar Fish	5 mg/L H_2O@; immersion	None	Anesthesia		25
Zebra Fish	10 mg/L $H_2O$$; immersion	None	Anesthesia		26

^Water tanks at temperature (72-77°F); pH (6.8-7.2); osmolality (38-45 mOsm/L)
#Dechlorinated water at temperature (63-65°F); pH (6.9-7.6), total ammonia (0.0-0.25 mg/L); nitrate (0.0-5.0 mg/L)
@Dechlorinated water at temperature 77 °F
$Water tank at temperature 80°F; pH 7.9

BIRDS

Common Name	ALFAXAN MULTIDOSE IDX Dose & Route	Concomitant Drug(s) Dose & Route	Outcome/ Comments	Precautions/ Adverse Reactions	Reference Number
Budgerigar	10 mg/kg; IM	None	Sedation		27
	15 mg/kg; IM	None	Sedation		28
Bengalese Finch	10, 30 & 50 mg/kg; SC	Midazolam 0.7 mg/kg or Butorphanol 1 mg/kg SC combined with 30 mg/kg ALFAXAN MULTIDOSE IDX; SC	Dose dependent response in duration of recumbency. Addition of midazolam or butorphanol produced a further increase in the duration of anesthesia.		29
Flamingo	2 mg/kg; IV	Isoflurane used for maintenance of anesthesia	Induction of anesthesia		30
Mute Swan	10 mg/kg; IV	Isoflurane used for maintenance of anesthesia	Induction of anesthesia	Induction apnea observed in 12% (median) of swans (n=27)	31

NON-HUMAN PRIMATES

Common Name	ALFAXAN MULTIDOSE IDX Dose & Route	Concomitant Drug(s) Dose & Route	Outcome/ Comments	Precautions/ Adverse Reactions	Reference Number
Ring Tailed Lemur	Initially 0.5 mg/kg; IV	Dexmedetomidine 0.015 mg/kg, Butorphanol 0.2 mg/kg, Midazolam 0.2 mg/kg; all IM	Bolused to effect until endotracheal intubation completed		32
Macaque	10 mg/kg; IM	Diazepam 3 mg/kg and Atropine 0.2 mg/kg IM	Supplemental bolus doses of 5 mg/kg ALFAXAN MULTIDOSE IDX administered IV to maintain anesthesia		33
Common Marmoset	12 mg/kg; IM	None	Sedation		34
	15 mg/kg; IM	None	Anesthesia		35
	12 to 18 mg/kg; IM	Diazepam 0.25 mg/kg; IM	Anesthesia		36
	18.5 mg/kg; IM	None	Anesthesia		37
	10.6 ± 1.6 mg/kg; IM	None	3.2±1.2 mg/kg administered IV after the IM dose		38

RODENTS

Common Name	ALFAXAN MULTIDOSE IDX Dose & Route	Concomitant Drug(s) Dose & Route	Outcome/ Comments	Precautions/ Adverse Reactions	Reference Number
Mice	15-20 mg/kg; IV	None	Anesthesia maintained with 0.25-0.75 mg/kg/min; IV		39
	80 mg/kg; IP	Xylazine 10 mg/kg; IP	Longer sleep times observed in female vs. male mice with ALFAXAN MULTIDOSE IDX ± xylazine IP	Mild seizure-like activity appeared in some mice	40
	60 mg/kg; SC	Medetomidine 0.3 mg/kg and Butorphanol 5 mg/kg; SC	Anesthesia	%Medetomidine should be used with caution in male mice (obstructive uropathy)	41
Rats	10-12 mg/kg; IV	None	Anesthesia maintained with 0.25-0.75 mg/kg/min; IV		39
	2-5 mg/kg; IV	None	Anesthesia produced IV	A 30% failure rate for anesthesia observed IP.	42
	20 mg/kg; IP				
	30 mg/kg/hr; IV	None	Maintenance of anesthesia		43
	25 mg/kg/hr; IP (females)	Dexmedetomidine 0.05 mg/kg IP or Dexmedetomidine 0.05 mg/kg + Fentanyl 0.1 mg/kg IP	Anesthesia. Males rats appeared to require more ALFAXAN MULTIDOSE IDX than female rats to produce a similar duration of anesthesia.		44
	75 mg/kg/hr; IP (males)				
	1.7 mg/kg/min for 2.5 min IV (induction of anesthesia)	None	Anesthesia maintained at 0.75 mg/kg/min; IV		45

Guinea Pig	5 mg/kg; IM	None	Sedation		46
	20 mg/kg; SC	+/- Dexmedetomidine 0.25 mg/kg; SC & Buprenorphine 0.05 mg/kg; SC	Sedation		47

[%]Wells S, et al. Urethral obstruction by seminal coagulum is associated with medetomidine-ketamine anesthesia in male mice on C57BL/6J and mixed genetic backgrounds. Am Assoc Lab Anim Sci 2009;48(3);296-299.

FERRETS

Common Name	ALFAXAN MULTIDOSE IDX Dose & Route	Concomitant Drug(s) Dose & Route	Outcome/ Comments	Precautions/ Adverse Reactions	Reference Number
Ferret	6 mg/kg; IM	Butorphanol 0.1 mg/kg and midazolam 1 mg kg/kg IM as premedication	Anesthesia maintained with 3 – 15 mg/kg/hr ALFAXAN MULTIDOSE IDX		48
	5 mg/kg; IV	Dexmedetomidine 0.05 mg/kg SC as premedication	Anesthesia		49
	5 mg/kg; IV	None	Anesthesia		50
	2.5 mg/kg; IV	Medetomidine 0.02 mg/kg IM as premedication			

MARSUPIALS

Common Name	ALFAXAN MULTIDOSE IDX Dose & Route	Concomitant Drug(s) Dose & Route	Outcome/ Comments	Precautions/ Adverse Reactions	Reference Number
Koala	3 mg/kg; IM	None	Anesthesia maintained with isoflurane in oxygen		51, 52, 53, 54, 55, 56
	2 mg/kg; IM	None	Anesthesia maintained with isoflurane in oxygen		57
	1.5 mg/kg; IV	None	Anesthesia		51
Wallaby	4 mg/kg; IM	Medetomidine 0.1 mg/kg; IM	Anesthesia. Drugs administered together in a dart.		58
Kangaroos and Wallabies	5-8 mg/kg; IM	None	Anesthesia		51
	1.5-3 mg/kg; IV				
Possums and Gliders	5-8 mg/kg; IM	None	Rapid and short duration of anesthesia produced.		51
	5 mg/kg; IV				
Wombats	3-5 mg/kg; IM	None	Anesthesia		51

MINOR SPECIES UNGULATES

Common Name	ALFAXAN MULTIDOSE IDX Dose & Route	Concomitant Drug(s) Dose & Route	Outcome/ Comments	Precautions/ Adverse Reactions	Reference Number
Alpaca	2.1 mg/kg; IV	None	Anesthesia achieved but poor quality of recovery observed.	Premedication is indicated prior to induction of anesthesia. Premedication will aid in induction of anesthesia and improve	59

				the quality of recovery in short procedures.	

DRUG INTERACTIONS

No specific preanesthetic is either indicated or contraindicated with ALFAXAN MULTIDOSE IDX. The necessity for and choice of preanesthetic is left to the discretion of the veterinarian. Preanesthetic doses may be lower than the label directions for their use as a single medication. ALFAXAN MULTIDOSE IDX is compatible with benzodiazepines, opioids, alpha$_2$-agonists, and phenothiazines as commonly used in surgical practice.

CONTRAINDICATIONS

ALFAXAN MULTIDOSE IDX is contraindicated in animals with a known sensitivity to ALFAXAN MULTIDOSE IDX or its components, or when general anesthesia and/or sedation are contraindicated. Do not use in any minor species animal that may become eligible for consumption by humans or food-producing animals.

WARNINGS

Animal Safety: Rapid bolus administration or anesthetic overdose may cause cardiorespiratory depression, including hypotension, apnea, hypoxia, or death. Arrhythmias may occur secondary to apnea and hypoxia. In cases of anesthetic overdose, stop ALFAXAN MULTIDOSE IDX administration and administer treatment as indicated by the patient's clinical signs. Cardiovascular depression should be treated with plasma expanders, pressor agents, anti-arrhythmic agents or other techniques as appropriate for the treatments of the clinical signs.

Human safety: Not for human use. Keep out of the reach of children.

ALFAXAN MULTIDOSE IDX should be managed to prevent the risk of diversion, through such measures as restriction of access and the use of drug accountability procedures appropriate to the clinical setting.

Exercise caution to avoid accidental self-injection. Overdose is likely to cause cardiorespiratory depression (such as hypotension, bradycardia and/or apnea). Remove the individual from the source of exposure and seek medical attention. Respiratory depression should be treated by artificial ventilation and oxygen. Avoid contact of this product with skin, eyes, and clothes. In case of contact, eyes and skin should be liberally flushed with water for 15 minutes. Consult a physician if irritation persists. In the case of accidental human ingestion, seek medical advice immediately and show the package insert or the label to the physician.

The Safety Data Sheet (SDS) contains more detailed occupational safety information. To report adverse reactions in users or to obtain a copy of the SDS for this product call 1-844-253-2926.

Note to physician: This product contains an injectable anesthetic.

DRUG ABUSE AND DEPENDENCE

Controlled substance: ALFAXAN MULTIDOSE IDX contains alfaxalone a neurosteroid anesthetic and a class IV controlled substance.

Abuse: Alfaxalone is a central nervous system depressant that acts on GABA receptor associated chloride channels, similar to the mechanism of action of Schedule IV sedatives such as benzodiazepines (diazepam and midazolam), barbiturates (phenobarbital and methohexital) and fospropofol. In a drug discrimination behavioral test in rats, the effects of alfaxalone were recognized as similar to those of midazolam. These biochemical and behavioral data suggest that alfaxalone has an abuse potential similar to other Schedule IV sedatives.

Physical dependence: There are no data that assess the ability of alfaxalone to induce physical dependence. However, alfaxalone has a mechanism of action similar to the benzodiazepines and can block the behavioral responses associated with precipitated benzodiazepine withdrawal. Therefore, it is likely that alfaxalone can also produce physical dependence and withdrawal signs similar to that produced by the benzodiazepines.

Psychological dependence: The ability of alfaxalone to produce psychological dependence is unknown because there are no data

on the rewarding properties of the drug from animal self-administration studies or from human abuse potential studies.

PRECAUTIONS

Analgesia during anesthesia: ALFAXAN MULTIDOSE IDX is not an analgesic and appropriate analgesia should be provided to the patient for painful procedures.

Rapid arousal: Careful monitoring of the patient is necessary due to possibility of rapid arousal.

Apnea: Apnea may occur following IV administration of an induction dose, maintenance dose or a dose administered during transition to inhalant maintenance anesthesia of ALFAXAN MULTIDOSE IDX, especially with higher doses and rapid administration. Endotracheal intubation, oxygen supplementation and intermittent positive pressure ventilation (IPPV) should be administered to treat apnea and associated hypoxemia in the appropriate species.

Blood Pressure: ALFAXAN MULTIDOSE IDX can exacerbate the myocardial depressive and vasodilatory effects of inhalant anesthetics resulting in hypotension. Preanesthetics can potentiate the effect of ALFAXAN MULTIDOSE IDX resulting in more pronounced changes in blood pressure. Transient hypertension has also been observed with ALFAXAN MULTIDOSE IDX administration, possibly due to elevated sympathetic activity in the patient. It is prudent to monitor blood pressure whenever possible.

Body temperature: Steps should be taken to maintain the normal physiological temperature of the patient during anesthesia. Supplemental heat, appropriate for the species, should be provided to maintain acceptable core body temperature until full recovery.

Breeding animals: Alfaxalone crosses the placenta, and as with other general anesthetic agents, the administration of ALFAXAN MULTIDOSE IDX may be associated with neonatal depression.

Compromised or debilitated animals: Caution should be used in animals with cardiac, respiratory, renal or hepatic impairment, or in hypovolemic or debilitated animals and geriatric animals.

ADVERSE REACTIONS

Specific adverse reactions described in the referenced literature are listed in the Dosage and Administration section of the product insert.

To report adverse reactions or to obtain a copy of the SDS for this product call 1-844-253-2926. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at http://www.fda.gov/reportanimalae.

OVERDOSE

Rapid administration, accidental overdose, or relative overdose due to inadequate dose sparing of ALFAXAN MULTIDOSE IDX in the presence of preanesthetics may cause cardiopulmonary depression. Respiratory arrest (apnea) may be observed. In cases of respiratory depression, stop drug administration, establish a patent airway, and initiate assisted or controlled ventilation with pure oxygen. Cardiovascular depression should be treated with plasma expanders, pressor agents, antiarrhythmic agents or other techniques as appropriate for the observed abnormality.

STORAGE INFORMATION: Store at controlled room temperature 20°C - 25°C (68° to 77°F) with excursions between 15° and 30°C (59° and 86°F). ALFAXAN MULTIDOSE IDX contains preservatives. The product can be used for 56 days after broaching the vial. Any unused ALFAXAN MULTIDOSE IDX remaining after 56 days should be discarded.

HOW SUPPLIED: ALFAXAN MULTIDOSE IDX is supplied in 10 and 20 mL multiple-dose vials containing 10 mg alfaxalone per mL.

Manufactured in Australia by Jurox Pty Ltd.

Marketed by: Jurox Inc.
North Kansas City, MO, 64116, USA
Phone 1-844-253-2926

Distributed by: Vedco Inc.
St Joseph, MO, 64507, USA

ALFAXAN is a registered trademark of Jurox Pty Ltd.

US Patent numbers 7,897,586 and 9,492,552

Sourced from: 470140 V02

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