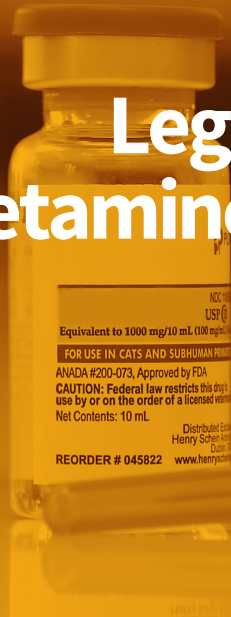


Legal Considerations of Ketamine for Veterinary Practices



FROM THE DESKS OF
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ISSUE

Ketamine is a short-acting, dissociative anesthetic used in both human and animal medicine for sedation. It allows for detachment of pain and the environment while providing hallucinogenic effects to the patient.¹ In 1999, ketamine became a schedule III non-narcotic substance under the Federal Controlled Substance Act.²

Because ketamine does not suppress breathing or lower blood pressure, it is a common, safe, injectable anesthetic used in veterinary medicine.² It is crucial that veterinarians have access to this drug, particularly in equine medicine.² The AVMA has urged the FDA not to restrict ketamine use in veterinary medicine because of its profound importance in practice.³

Ketamine has become widely popular as a recreational drug because of its fast-acting psychotropic effects, duration period, and low cost.⁴⁻⁶ Recreational use of this drug is concerning because of the risk for adverse events, which can include panic attacks, depression, exacerbated mental health conditions, weight loss, and poor appetite.⁵

In addition, ketamine is one of several drugs with depressant effects, including confusion, bradycardia, vertigo, lethargy, impaired judgment, amnesia, ataxia, loss of consciousness, syncope, nausea, hypotension, and loss of inhibition and is often used to facilitate sexual assault in humans.⁴

In 2015, the World Health Organization decided that ketamine should not become internationally scheduled, as it does not pose a significant public health threat in terms of illicit use, and that, therefore, it should remain easily accessible to both human and veterinary medical professionals.² For humans wanting the drug for illicit use, veterinary clinics are a prime target for robbery.⁷

Veterinarians should be aware of the licit and illicit aspects of ketamine, how to deter and report theft associated with illicit demand and weak regulations, and the legal requirements surrounding the use of this controlled substance.

ANSWER

FEDERAL & STATE LAWS

Federal law for controlled substances mandates that “all applicants and registrants provide effective controls and procedures to guard against theft and diversion of controlled substances”⁸ and that “controlled substances listed in schedules II, III, IV, and V shall be stored in a securely locked, substantially constructed cabinet.”⁹ A Drug Enforcement Administration (DEA)-registered veterinarian cannot allow access to controlled substances to an employee who has been denied a DEA registration, been convicted of a felony related to controlled substances, or had his or her DEA registration revoked or suspended.⁸

Every practitioner must maintain separate inventories and records of schedules III, IV, and V controlled substances separate from schedules I and II.¹⁰ The DEA requires that all controlled substance inventory records be updated every 2 years and be available for inspection.¹⁰

In addition to federal requirements, each state has its own requirements for record keeping, physical security, disposal, and inventory of controlled substances. Veterinarians are encouraged to contact their state’s controlled substance authority (eg, state board of pharmacy) to learn the legal requirements for possessing and using ketamine.

Penalties for violating state and/or federal regulations can result in suspension or revocation of the dispenser’s federal controlled substance registration¹¹ as well as the state controlled substance registration.

Disposal

Veterinarians with unused ketamine stock should check with their supplier about returns for credit or disposal. If those are unavailable, the DEA uses licensed companies to take the drug;

contact information for authorized companies is available from local DEA offices. Practitioners should maintain copies of records documenting the transfer and disposal of controlled substances for at least 2 years.¹⁰ Individual states may have additional requirements for ketamine disposal.

PREVENTING & REPORTING THEFT

The authors recommend the following steps to prevent theft of ketamine from the clinic:

- ▶ Keep a perpetual inventory, as well as a detailed record of drug use by each patient and the addition of new inventory to demonstrate exactly how much ketamine should be in inventory.
- ▶ Perform random checks to ensure inventory records match physical inventory.
- ▶ Always have at least 2 team members oversee drug ordering and inventory.
- ▶ Store ketamine in a sturdy locked cabinet or safe.
- ▶ Dispose of expired ketamine immediately in an approved manner.
- ▶ Keep only the needed quantity of ketamine on hand; do not order large amounts that may be unused for long periods of time.
- ▶ Review security protocols regularly, including staff access.

Veterinarians should notify the nearest DEA Field Division Office within one business day of any theft or significant loss of controlled substances,¹² as well as immediately report the theft to their state’s controlled substance authority and police.¹³

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GALLIPRANT® (grapiprant tablets)

For oral use in dogs only

20 mg, 60 mg and 100 mg flavored tablets

A prostaglandin E₂ (PGE₂) EP₄ receptor antagonist; a non-cyclooxygenase inhibiting, non-steroidal anti-inflammatory drug

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

Before using this product, please consult the product insert, a summary of which follows:

Indication: GALLIPRANT (grapiprant tablets) is indicated for the control of pain and inflammation associated with osteoarthritis in dogs.

Dosage and Administration: Always provide "Information for Dog Owners" Sheet with prescription. Use the lowest effective dose for the shortest duration consistent with individual response.

The dose of GALLIPRANT (grapiprant tablets) is 0.9 mg/lb (2 mg/kg) once daily.

GALLIPRANT tablets are scored and dosage should be calculated in half tablet increments. Dogs less than 8 lbs (3.6 kgs) cannot be accurately dosed. **See product insert for complete dosing and administration information.**

Contraindications: GALLIPRANT should not be used in dogs that have a hypersensitivity to grapiprant.

Warnings: Not for use in humans. Keep this and all medications out of reach of children and pets. Consult a physician in case of accidental ingestion by humans. **For use in dogs only.** Store GALLIPRANT out of reach of dogs and other pets in a secured location in order to prevent accidental ingestion or overdose.

Precautions: The safe use of GALLIPRANT has not been evaluated in dogs younger than 9 months of age and less than 8 lbs (3.6 kg), dogs used for breeding, or in pregnant or lactating dogs. Adverse reactions in dogs receiving GALLIPRANT may include vomiting, diarrhea, decreased appetite, mucoid, watery or bloody stools, and decreases in serum albumin and total protein.

If GALLIPRANT is used long term, appropriate monitoring is recommended.

Concurrent use with other anti-inflammatory drugs has not been studied. Concomitant use of GALLIPRANT with other anti-inflammatory drugs, such as COX-inhibiting NSAIDs or corticosteroids, should be avoided. If additional pain medication is needed after a daily dose of GALLIPRANT, a non-NSAID/non-corticosteroid class of analgesic may be necessary.

The concomitant use of protein-bound drugs with GALLIPRANT has not been studied. Commonly used protein-bound drugs include cardiac, anticonvulsant and behavioral medications.

Drug compatibility should be monitored in patients requiring adjunctive therapy. Consider appropriate washout times when switching from one anti-inflammatory to another or when switching from corticosteroids or COX-inhibiting NSAIDs to GALLIPRANT use.

The use of GALLIPRANT in dogs with cardiac disease has not been studied.

It is not known whether dogs with a history of hypersensitivity to sulfonamide drugs will exhibit hypersensitivity to GALLIPRANT. GALLIPRANT is a methylbenzenesulfonamide.

Adverse Reactions: In a controlled field study, 285 dogs were evaluated for safety when given either GALLIPRANT or a vehicle control (tablet minus grapiprant) at a dose of 2 mg/kg (0.9 mg/lb) once daily for 28 days. GALLIPRANT-treated dogs ranged in age from 2 yrs to 16.75 years. The following adverse reactions were observed:

Adverse reaction*	GALLIPRANT (grapiprant tablets) N = 141	Vehicle control (tablets minus grapiprant) N = 144
Vomiting	24	9
Diarrhea, soft stool	17	13
Anorexia, inappetence	9	7
Lethargy	6	2
Buccal ulcer	1	0
Immune mediated hemolytic anemia	1	0

*Dogs may have experienced more than one type or occurrence during the study.

GALLIPRANT was used safely during the field studies with other concurrent therapies, including antibiotics, parasiticides and vaccinations.

To report suspected adverse drug events and/or obtain a copy of the Safety Data Sheet (SDS) or for technical assistance, call 1-888-545-5973.

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/AnimalVeterinary/SafetyHealth>

Information for Dog Owners: Owners should be advised of the potential for adverse reactions and be informed of the clinical signs associated with drug intolerance. Adverse reactions may include vomiting, diarrhea, decreased appetite, and decreasing albumin and total protein. Appetite and stools should be monitored and owners should be advised to consult with their veterinarian if appetite decreases or stools become abnormal.

Effectiveness: Two hundred and eighty five (285) client-owned dogs were enrolled in the study and evaluated for field safety. GALLIPRANT-treated dogs ranging in age from 2 to 16.75 years and weighing between 4.1 and 59.6 kgs (9-131 lbs) with radiographic and clinical signs of osteoarthritis were enrolled in a placebo-controlled, masked field study. Dogs had a 7-day washout from NSAID or other current OA therapy. Two hundred and sixty two (262) of the 285 dogs were included in the effectiveness evaluation. Dogs were assessed for improvements in pain and function by the owners using the Canine Brief Pain Inventory (CBPI) scoring system.¹ A statistically significant difference in the proportion of treatment successes in the GALLIPRANT group (63/131 or 48.1%) was observed compared to the vehicle control group (41/131 or 31.3%). GALLIPRANT demonstrated statistically significant differences in owner assessed pain and function. The results of the field study demonstrate that GALLIPRANT, administered at 2 mg/kg (0.9 mg/pound) once daily for 28 days was effective for the control of pain and inflammation associated with osteoarthritis.

Storage Conditions: Store at or below 86° F (30° C)

How Supplied: 20 mg, 60 mg, 100 mg flavored tablets in 7, 30 and 90 count bottles.



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