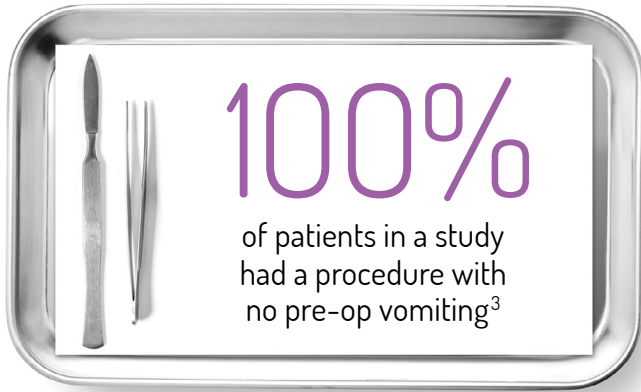


Is Emesis Your Nemesis?

CERENIA® (maropitant citrate) can help your canine patients — and your team — by preventing vomiting due to opioids during spay, neuter, dental and other common procedures.^{1,2}



Research and in-clinic use show that when CERENIA is added to canine preoperative protocols:



of owners would pay for preoperative antiemetic. Fifty-three owners (51.4 %) would definitely and 49 /103 (47.6 %) would probably choose treatment to prevent vomiting (total 99 %).⁴

“When patient calls were done the following day, owners repeatedly said, ‘Thank you! My dog ate!’ This is helping improve relationships between practice and clients as well as owner and pet.”

Adam Christman, DVM
Brick, N.J.

See study results and
read more from your peers:
preventemesis.com

IMPORTANT SAFETY INFORMATION: Use CERENIA Injectable subcutaneously for acute vomiting in dogs 2 to 4 months of age or either subcutaneously or intravenously in dogs 4 months of age and older. Safe use has not been evaluated in cats and dogs with gastrointestinal obstruction, or those that have ingested toxins. Use with caution in dogs with hepatic dysfunction. Pain and vocalization upon injection is a common side effect. In people, topical exposure may elicit localized allergic skin reactions, and repeated or prolonged exposure may lead to skin sensitization. See full Prescribing Information, attached.

*Return to normal feeding was the time at which 100 grams of food was consumed.

1. Data on file, Study Report TI-033333.

2. Study Report No. 1961R-60-11-A81

3. Ramsey D., Fleck T., Berg T. et al. Cerenia prevents perioperative nausea and vomiting and improves recovery in dogs undergoing routine surgery. Inter J Appl Res Vet Med. 2014; 12 (3):229-238.

4. Kraus, BLH, Cazian C. Assessment of dog owner concern regarding peri-operative nausea and vomiting and willingness to pay for anti-emetic treatment. Front Vet Sci. 2019; 6:264

Cerenia[®]

(maropitant citrate)

Tablets and Injectable Solution

Antiemetic

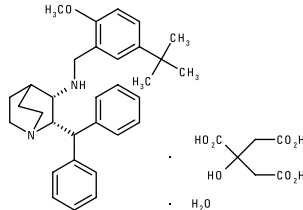
CERENIA Tablets
For oral use in dogs only

CERENIA Injectable
For subcutaneous or intravenous injection in dogs and cats

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

DESCRIPTION: Maropitant is a neurokinin (NK₁) receptor antagonist that blocks the pharmacological action of substance P in the central nervous system (CNS). Maropitant is the non-proprietary designation for a substituted quinuclidine. The empirical formula is C₂₂H₂₆N₂O, C₂₆H₃₀O, H₂O and the molecular weight 678.81. The chemical name is (2S,3S)-2-benzhydryl-N-(5-*tert*-butyl-2-methoxybenzyl) quinuclidin-3-amine citrate monohydrate. Each peach-colored oval tablet is scored and contains 16, 24, 60 or 160 mg of maropitant as maropitant citrate per tablet. Each mL of CERENIA Injectable Solution contains 10 mg maropitant, 63 mg sulphobutylether-beta-cyclodextrin, 3.3 mg meta-cresol and water for injection.

The chemical structure of maropitant citrate is:



INDICATIONS: CERENIA (maropitant citrate) Tablets are indicated for the prevention of acute vomiting and the prevention of vomiting due to motion sickness in dogs. CERENIA (maropitant citrate) Injectable Solution is indicated for the prevention and treatment of acute vomiting in dogs and for the treatment of vomiting in cats.

DOSE AND ADMINISTRATION:

For Prevention of Acute Vomiting (CERENIA Tablets)

For Prevention of Acute Vomiting in dogs 2-7 months of age: Administer CERENIA Tablets orally at a minimum dose of 2 mg/kg (0.9 mg/lb) body weight once daily for up to 5 consecutive days (see WARNINGS and Animal Safety).

For Prevention of Acute Vomiting in dogs 7 months of age and older: Administer CERENIA Tablets orally at a minimum dose of 2 mg/kg (0.9 mg/lb) body weight once daily until resolution of acute vomiting.

If vomiting persists despite treatment, the case should be re-evaluated. CERENIA is most effective in preventing acute vomiting associated with chemotherapy if administered prior to the chemotherapeutic agent.

For prevention of acute vomiting, dispense whole or half tablets in strength(s) that most closely result in a 2 mg/kg dose:

Dog body weight		Number of Tablets		
Pounds	Kilograms	16 mg	24 mg	60 mg
8	4	1/2		
15	8	1		
25	12		1	
50	24		2	
65	30			1
130	60			2

Interchangeable use with CERENIA Injectable Solution for Prevention of Acute Vomiting:

In dogs that are actively vomiting, to ensure that the full initial dose is administered, CERENIA Injectable Solution is recommended at a dose of 1 mg/kg once daily. Thereafter, for the prevention of acute vomiting, CERENIA Tablets at a dose of 2 mg/kg once daily may be used interchangeably with CERENIA Injectable Solution for up to 5 days.

For Prevention of Vomiting Due to Motion Sickness in dogs 4 months and older (CERENIA Tablets)

For Prevention of Vomiting due to motion sickness in dogs 4 months of age and older: Administer CERENIA Tablets orally at a minimum dose of 8 mg/kg (3.6 mg/lb) body weight once daily for up to 2 consecutive days (see WARNINGS and Animal Safety).

Administer CERENIA Tablets a minimum of two hours prior to travel with a small amount of food to mitigate vomiting associated with administration of the dose on an empty stomach; however, refrain from feeding a full meal prior to travel.

Prevention of Vomiting Due to Motion Sickness in Dogs 4 months of age and older:

Dispense whole or half tablets in strengths that most closely result in an 8 mg/kg dose once daily for up to 2 consecutive days:

Dog body weight		Number of Tablets			
Pounds	Kilograms	16 mg	24 mg	60 mg	160 mg
2	1	1/2			
3	1.5		1/2		
4	2	1			
6	3		1		
8	4	2			
13	6		2		
16	7.5			1	
22	10				1/2
33	15			2	
44	20				1
66	30				1 1/2
88	40				2
132	60				3

CERENIA Injectable Solution should not be used interchangeably with CERENIA Tablets for the prevention of vomiting due to motion sickness (8mg/kg).

For Prevention and Treatment of Acute Vomiting in Dogs (CERENIA Injectable):

Dogs 2-4 Months of Age: Administer CERENIA Injectable Solution subcutaneously at 1 mg/kg (0.45 mg/lb) equal to 0.1 mL/kg (0.1 mL/2.2 lb) of body weight once daily for up to 5 consecutive days.

Dogs 4 months of Age and Older: Administer CERENIA Injectable Solution intravenously over 1-2 minutes or subcutaneously at 1 mg/kg (0.45 mg/lb) equal to 0.1 mL/kg (0.1 mL/2.2 lb) of body weight once daily for up to 5 consecutive days.

In dogs that are actively vomiting, it is recommended to initiate treatment with CERENIA Injectable Solution. Thereafter, CERENIA Tablets may be used for the prevention of acute vomiting at 2 mg/kg once daily. (See CERENIA Tablets package insert for complete prescribing information).

For Prevention of Vomiting in Dogs 4 months of Age and Older Caused by Emetogenic Medications or Chemotherapeutic Agents: Administer CERENIA Injectable Solution intravenously over 1-2 minutes or subcutaneously at 1 mg/kg (0.45 mg/lb) of body weight one time, 45-60 minutes prior to use of emetogenic medications or chemotherapeutic agents.

For Treatment of Vomiting in Cats 4 Months of Age and Older (CERENIA Injectable):

Administer CERENIA Injectable Solution intravenously over 1-2 minutes or subcutaneously at 1 mg/kg (0.45 mg/lb) equal to 0.1 mL/kg (0.1 mL/2.2 lb) of body weight once daily for up to 5 consecutive days.

The underlying cause of acute vomiting should be identified and addressed in dogs and cats that receive CERENIA Injectable Solution. If vomiting persists despite treatment, the case should be re-evaluated.

INFORMATION FOR USE: If vomiting persists despite treatment, the case should be re-evaluated. CERENIA is most effective in preventing vomiting associated with chemotherapy if administered prior to the chemotherapeutic agent.

For dogs, CERENIA Injectable Solution may be used interchangeably with CERENIA Tablets for once daily dosing for the prevention of acute vomiting.

WARNINGS: Not for use in humans. Keep out of the reach of children. In case of accidental ingestion, seek medical advice. Topical exposure may elicit localized allergic skin reactions in some individuals. Repeated or prolonged exposure may lead to skin sensitization. Wash hands with soap and water after administering drug. CERENIA is also an ocular irritant. In case of accidental eye exposure, flush with water for 15 minutes and seek medical attention.

In puppies younger than 11 weeks of age, histological evidence of bone marrow hypocellularity was observed at higher frequency and greater severity in puppies treated with CERENIA compared to control puppies. In puppies 16 weeks and older, bone marrow hypocellularity was not observed (see **ANIMAL SAFETY**).

PRECAUTIONS: The safe use of CERENIA Tablets has not been evaluated in dogs or cats used for breeding, or in pregnant or lactating bitches or queens. The safe use of CERENIA Injectable Solution has not been evaluated in dogs or cats with gastrointestinal obstruction or that have ingested toxins.

Use with caution in patients with hepatic dysfunction because CERENIA Injectable Solution is metabolized by CYP3A, CYP2D15 (dogs) and CYP1A (cats) enzymes (see **Pharmacokinetics**). The influence of concomitant drugs that may inhibit the metabolism of CERENIA Injectable Solution has not been evaluated. CERENIA Injectable Solution is highly protein bound. Use with caution with other medications that are highly protein bound. The concomitant use of CERENIA Injectable Solution with other protein bound drugs has not been studied in dogs or cats. Commonly used protein bound drugs include NSAIDs, cardiac, anticonvulsant, and behavioral medications. Drug compatibility should be monitored in patients requiring adjunctive therapy.

CERENIA Tablets causes dose related decreases in appetite and body weight (see **ANIMAL SAFETY**). To maximize therapeutic potential of CERENIA Tablets, the underlying cause of vomiting should be identified and addressed in dogs receiving CERENIA Tablets.

The safe use of CERENIA Injectable Solution has not been evaluated in dogs or cats used for breeding, or in pregnant or lactating bitches or queens.

ADVERSE REACTIONS:

Prevention of Acute Vomiting (minimum of 2 mg/kg) (CERENIA Tablets)

The following adverse reactions were reported during the course of a US field study for the prevention of acute vomiting in dogs treated with CERENIA Tablets at a minimum of 2 mg/kg orally and/or Injectable Solution at 1 mg/kg subcutaneously once daily for up to 5 consecutive days:

Frequency of Adverse Reactions by Treatment

Adverse Reaction	Placebo (n=69)		CERENIA (n=206)	
	# dogs	% occurrence	# dogs	% occurrence
Death during study	4	5.8	10	4.9
Euthanized during study	0	0	2	1
Diarrhea	6	8.7	4	3.9
Hematochezia/bloody stool	5	7.2	8	1.9
Anorexia	2	2.9	3	1.5
Otitis/Otorrhea	0	0	3	1.5
Endotoxic Shock	1	1.4	2	1
Hematuria	0	0	2	1
Excoriation	0	0	2	1

Other clinical signs were reported but were <0.5% of dogs.

Prevention of Vomiting Due to Motion Sickness (minimum of 8 mg/kg) (CERENIA Tablets)

The following adverse reactions were reported during US studies for the prevention of vomiting due to motion sickness in dogs treated with CERENIA Tablets at a minimum of 8 mg/kg orally one time. Dogs may have experienced more than one of the observed adverse reactions.

Frequency of Adverse Reactions by Treatment

Adverse Reaction	Placebo (n=195)		CERENIA (n=208)	
	# dogs	% occurrence	# dogs	% occurrence
Hypersalivation	19	9.7	26	12.5
Vomiting ¹	0	0	11	5.3
Muscle Tremors	1	0.5	2	1
Sedation/Depression	3	1.5	2	1
Retching	3	1.5	1	0.5
Flatulence	0	0	1	0.5

¹ Not associated with motion sickness

The following adverse reactions were reported during a European field study for the prevention of vomiting due to motion sickness in dogs treated with CERENIA Tablets at a minimum of 8 mg/kg orally once daily for 2 consecutive days. Dogs may have experienced more than one of the observed adverse reactions.

Frequency of Adverse Reactions by Treatment

Adverse Reaction	Placebo (n=106)		CERENIA (n=107)	
	# dogs	% occurrence	# dogs	% occurrence
Vomiting	4	4	10	9
Drowsiness/Lethargy/Apathy	1	1	8	8
Hypersalivation	2	2	5	5
Anxiety	0	0	2	2
Trembling/Tremors	0	0	2	2
Inappetence	0	0	2	2
Mucus in stool	0	0	1	1

The following Adverse Reactions were reported during the conduct of a US clinical field trial where CERENIA Tablets were administered once daily for 28 consecutive days to 32 dogs: lethargy, vomiting, inappetence, corneal edema, and enlarged lymph nodes.

Post-Approval Experience (CERENIA Tablets - Revised May 2019)

The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse events are reported to FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using these data.

The following adverse events reported for dogs are listed in decreasing order of frequency: anorexia, depression/lethargy, hypersalivation, vomiting, diarrhea, trembling, ataxia, allergic reactions, weight loss, convulsion, hyperactivity, and panting.

Cases of ineffectiveness have been reported.

Cases of death (including euthanasia) have been reported.

To report suspected adverse events, for technical assistance or to obtain a copy of the SDS, contact Zoetis Inc. at 1-888-963-8471 or www.zoetis.com.

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>.

(CERENIA Injectable):

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>.

For a complete listing of adverse reactions for CERENIA Injectable Solution reported to CVM see: <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm055369.htm>

For a copy of the Material Safety Data Sheet (MSDS) or to report adverse reactions call Zoetis Inc. at 1-888-963-8471.

DOGS:

In a US field study for the prevention and treatment of vomiting associated with administration of cisplatin for cancer chemotherapy, the following adverse reactions were reported in 77 dogs treated with CERENIA Injectable Solution at 1 mg/kg subcutaneously or 41 dogs treated with placebo:

Frequency of Adverse Reactions by Treatment

Adverse Reaction	Placebo (n=41)		CERENIA (n=77)	
	# dogs	% occur	# dogs	% occur
Diarrhea	1	2.4	6	7.8
Anorexia	0	0	4	5.2
Injection site reaction (swelling, pain upon injection)	0	0	3	4
Lethargy	1	2.4	2	2.6

The following adverse reactions were reported during the course of a US field study for the prevention and treatment of acute vomiting in dogs treated with 1 mg/kg CERENIA Injectable Solution subcutaneously and/or CERENIA Tablets at a minimum of 2 mg/kg orally once daily for up to 5 consecutive days:

