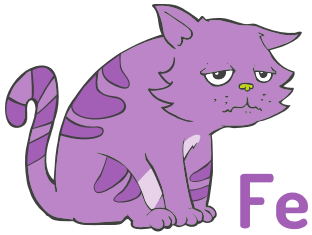
Reliable and Flexible Dosing

Cerenia®
maropitant citrate



Feline

Canine

	Feline	Canine					
	INJECTABLE	INJECTABLE			TABLETS		
Indication	Treatment of vomiting	For prevention and treatment of acute vomiting		For prevention of vomiting caused by emetogenic medications or chemotherapeutic agents	For prevention of acute vomiting		For prevention of vomiting due to motion sickness
Age	4 months and older	2-4 months of age	4 months and older	4 months and older	2-7 months of age	7 months and older	4 months and older
Dose & Administration	1mg/kg IV over 1-2 minutes or SC once daily up to 5 consecutive days*	1mg/kg SC once daily up to 5 consecutive days*	1mg/kg IV over 1-2 minutes or SC once daily up to 5 consecutive days*	1mg/kg IV over 1-2 minutes or SC, administered 45-60 minutes prior to use of emetogenic medication or chemotherapeutic agent	2mg/kg once daily up to 5 consecutive days*	2mg/kg once daily until resolution of acute vomiting*	8mg/kg once daily for up to 2 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 2mg/kg once daily.

*If vomiting persists despite treatment, the case should be re-evaluated.

IMPORTANT SAFETY INFORMATION: Use Cerenia Injectable for vomiting in cats 4 months and older; use 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. Use Cerenia Tablets for acute vomiting in dogs 2 months and older, and for prevention of vomiting due to motion sickness in dogs 4 months 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 cats and dogs with hepatic dysfunction. Pain/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.

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Brief Summary of full Prescribing Information

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.

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.

DOSAGE AND ADMINISTRATION (CERENIA Tablets):
For Prevention of Acute Vomiting:

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).

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: 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).

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).

DOSAGE AND ADMINISTRATION (CERENIA Injectable):
Use of refrigerated product may reduce the pain response associated with subcutaneous injection.

Dogs:

For Prevention and Treatment of Acute Vomiting in Dogs:

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/1 kg (1 mL/22 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.

Cats:

For Treatment of Vomiting in Cats 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.

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.

WARNINGS: Not for use in humans. Keep out of the reach of children. In case of accidental ingestion, injection, or exposure, 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 and in case of accidental skin exposure. 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.

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

The safe use of CERENIA 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 is metabolized by CYP3A, CYP2D15 (dogs) and CYP1A (cats) enzymes. The influence of concomitant drugs that may inhibit the metabolism of CERENIA has not been evaluated. CERENIA is highly protein bound. Use with caution with other medications that are highly protein bound. The concomitant use of CERENIA 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. To maximize therapeutic potential of CERENIA Tablets, the underlying cause of vomiting should be identified and addressed in dogs receiving CERENIA Tablets.

ADVERSE REACTIONS:
CERENIA Tablets
Prevention of Acute Vomiting (minimum of 2 mg/kg)
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	8	3.9
Hematochezia/ bloody stool	5	7.2	4	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)
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 (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 www.fda.gov/reportanimalae.

ADVERSE REACTIONS:
CERENIA Injectable
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:

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	8	3.9
Hematochezia/bloody stool	5	7.2	4	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.

Adverse reactions seen in a European field study included ataxia, lethargy and injection site soreness in one dog treated with CERENIA Injectable Solution.

Post-Approval Experience (Rev. 2015)
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 reporting frequency for CERENIA Injectable Solution: Pain/vocalization upon injection, depression/ lethargy, anorexia, anaphylaxis/anaphylactoid reactions (including swelling of the head/face), ataxia, convulsions, hypersalivation, tremors, fever, dyspnea, collapse/loss of consciousness, recumbency, injection site reactions (swelling, inflammation) and sedation.

Cases of death (including euthanasia) have been reported.

CATS (CERENIA Injectable Solution):
The following adverse reactions were reported during the course of a US field study for the treatment of vomiting in cats treated with 1 mg/kg CERENIA Injectable Solution subcutaneously once daily for up to five consecutive days:

Frequency of Adverse Reactions by Treatment

Adverse Reaction	Placebo (n=62)		CERENIA (n=133)	
	# cats	% occurrence	# cats	% occurrence
Moderate Response to Injection[1,2]	1	1.6	30	22.6
Significant Response to Injection[1,3]	1	1.6	15	11.3
Fever/Pyrexia	2	3.2	2	1.5
Dehydration	0	0	3	2.3
Lethargy	0	0	2	1.5
Anorexia	0	0	1	0.8
Hematuria	0	0	1	0.8
Hypersalivation	0	0	1	0.8
Injection site swelling	1	1.6	0	0

[1] The clinician observed and graded each cat's response to injection.
[2] Cat objected to the injection by retreating and vocalizing
[3] Cat objected to the injection by retreating, hissing, scratching, and vocalization

Post-Approval Experience (Rev. 2015)
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 cats are listed in decreasing order of reporting frequency for CERENIA Injectable Solution: Depression/lethargy, anorexia, hypersalivation, pain/ vocalization upon injection, dyspnea, ataxia, fever, recumbency, vomiting, panting, convulsion, and muscle tremor.

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 www.fda.gov/reportanimalae.

STORAGE CONDITIONS:
CERENIA Tablets should be stored at controlled room temperature 20°–25°C (68°–77°F) with excursions between 15°–30°C (59°–86°F).

CERENIA Injectable Solution should be stored at or below 30°C (86°F), with excursions permitted up to 40°C (104°F). After first vial puncture, CERENIA Injectable Solution should be stored at refrigerated temperature 2-8°C (36-46°F). Use within 90 days of first vial puncture. Stopper may be punctured a maximum of 25 times.

HOW SUPPLIED:
CERENIA peach-colored tablets are scored with a break line, and contain 16, 24, 60 or 160 mg of maropitant as maropitant citrate per tablet. Each tablet is marked with "MPT" and the tablet strength.

Each tablet size is available in the following strengths and are supplied in blister packs containing 4 tablets:
16 mg contains 10 blisters per carton (40 tablets)
24 mg contains 10 blisters per carton (40 tablets)
60 mg contains 10 blisters per carton (40 tablets)
160 mg contains 5 blisters per carton (20 tablets)

CERENIA Injectable Solution is supplied in 20 mL amber glass vials. Each mL contains 10 mg of maropitant as maropitant citrate.

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Distributed by:
Zoetis Inc.
Kalamazoo MI 49007

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