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## Cerenia Tablets for dogs

Species:	Dogs
Therapeutic indication:	<b>Pharmaceuticals:</b> Miscellaneous
Active ingredient:	Maropitant
Product:	Cerenia® Tablets for dogs
Product index:	Cerenia Tablets

## Presentation

Each tablet contains 16 mg, 24 mg, 60 mg or 160 mg maropitant as maropitant citrate monohydrate. The tablets also contain Sunset Yellow (E110) as a colourant.

The tablets are pale orange and have a score line on both sides allowing the tablet to be halved. Each tablet is marked with the Pfizer logo on the reverse side. On the obverse side, each half is marked with the letters "MPT" and figures denoting the quantity of maropitant.

## Uses

Cerenia tablets are indicated for the following:

- For the prevention of nausea induced by chemotherapy.
- For the treatment and prevention of vomiting, in conjunction with Cerenia Solution for Injection and in combination with other supportive measures.
- For the prevention of vomiting induced by motion sickness.

## Dosage and administration

For oral use in dogs.

## For the prevention of nausea induced by chemotherapy and treatment and prevention of vomiting (except motion sickness) in dogs aged 8 weeks of age or older

Cerenia tablets should be administered once daily, at a dose of 2 mg maropitant per kg bodyweight, using the number of tablets given in the table below. Tablets are breakable along the score line on the tablet.

To prevent vomiting, tablets should be given more than 1 hour in advance. The duration of the effect is approximately 24 hours and, therefore, tablets can be given the night before administration of an agent that may cause emesis (e.g. chemotherapy).

Cerenia can be used as either tablets or Solution for Injection once daily. Cerenia Solution for Injection may be administered for up to five days and Cerenia Tablets for up to 14 days.

Cerenia tablets are effective in the treatment of vomiting, however in cases of frequent vomiting it is recommended to initiate treatment with Cerenia Solution for Injection.

Prevention of nausea induced by chemotherapy Treatment and prevention of vomiting (except motion sickness)			
Dog bodyweight (kg)	Number of tablets		
	16 mg	24 mg	60 mg
3.0 – 4.0*	1/2		
4.1 – 8.0	1		
8.1 – 12.0		1	
12.1 – 24.0		2	
24.1 – 30.0			1
30.1 – 60.0			2

\* Correct dose for dogs of less than 3 kg cannot be accurately achieved.

## For prevention of vomiting induced by motion sickness in dogs aged 16 weeks of age or older

Cerenia tablets should be administered once daily, at a dose of 8 mg maropitant per kg bodyweight, using the numbers of tablets given in the table below. Tablets are breakable along the score line on the tablet.

Tablets should be administered at least one hour before starting the journey. The anti-emetic effect persists for at least 12 hours, which for convenience may allow administration the night before early morning travel. Treatment may be repeated for a maximum of two consecutive days.

In some individual dogs and when repeating the treatment, lower doses than recommended might be sufficient.

Prevention of motion sickness only				
Dog bodyweight (kg)	Number of tablets			
	16 mg	24 mg	60 mg	160 mg
1.0 – 1.5		1/2		
1.6 – 2.0	1			
2.1 – 3.0		1		
3.1 – 4.0	2			
4.1 – 6.0		2		
6.1 – 7.5			1	
7.6 – 10.0				1/2
10.1 – 15.0			2	
15.1 – 20.0				1
20.1 – 30.0				1 1/2
30.1 – 40.0				2
40.1 – 60.0				3

To remove a tablet from the blister the following sequence should be carried out;

- Firstly, fold or cut along the perforation between each tablet as shown by the scissor symbol.
- Find the pull-back notch (or cut) as shown by the arrow symbol.
- Holding one side of the cut firmly, pull the other side towards the centre of the blister until the tablet is visible.
- Remove tablet from blister and administer as instructed.

*Note:* No attempt should be made to remove the tablet by pushing it through the blister backing as this will damage both the tablet and blister.

A light meal or snack before dosing is recommended; prolonged fasting before administration should be avoided. Cerenia tablets should not be administered wrapped or encapsulated in food as this may delay dissolution of the tablet and consequently the onset of the effect.

Dogs should be carefully observed following administration to ensure that each tablet is swallowed.

## Contra-indications, warnings, etc

Vomiting can be associated with serious, severely debilitating conditions including gastrointestinal obstructions; therefore, appropriate diagnostic evaluations should be employed.

Administering Cerenia on a completely empty stomach may cause the dog to vomit. A light snack before dosing could help prevent this effect.

The safety of Cerenia has not been established in dogs less than 16 weeks of age (for the 8 mg/kg dose: motion sickness) and in dogs less than 8 weeks of age (for the 2 mg/kg dose: vomiting), as well as in pregnant or lactating bitches. Use only according to a risk benefit assessment by the responsible veterinary surgeon.

Cerenia should be used in conjunction with other supportive measures if appropriate.

Cerenia tablets were well tolerated when administered for 15 days at dosages up to 10 mg/kg bodyweight per day. Clinical signs including vomiting on first administration, excess salivation and watery faeces have been observed when the product has been overdosed in excess of 20 mg/kg.

The safety of maropitant during treatment beyond 5 days has not been explored in young dogs with viral enteritis. In case treatment for a longer period than 5 days is required, careful monitoring of potential adverse events should be implemented.

Maropitant is metabolised in the liver and therefore should be used with caution in dogs with liver disease. As maropitant is accumulated in the body during a 14 day treatment period due to metabolic saturation, careful monitoring of liver function in addition to any adverse events should be implemented during long term treatment.

Cerenia should be used with caution in animals suffering from or with a predisposition for heart diseases. Cerenia should not be used concomitantly with Ca-channel antagonists as maropitant has affinity to Ca-channels.

Maropitant is highly bound to plasma proteins and may compete with other highly bound drugs.

Cerenia is not a sedative and some motion sick dogs may show nausea-like signs during travel such as salivation and lethargy. These signs are temporary and should resolve when the journey ends.

Incidents of pre-travel vomiting, usually within two hours post-dosing, were commonly reported (more than 1 but less than 10 animals in 100 animals treated) after administration of the 8 mg/kg

dose.

## User warnings

People with known hypersensitivity to maropitant should administer the veterinary medicinal product with caution.

Wash hands after use. In case of accidental ingestion seek medical advice immediately and show the package leaflet or the label to the physician.

## Pharmaceutical precautions

This veterinary medicinal product does not require any special storage conditions.

Half-tablets should be stored for a maximum of two days after removal from the blister. Half-tablets should be returned to the opened blister and kept within the cardboard outer.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Keep out of the sight and reach of children.

For animal treatment only.

## Legal category

Legal category: POM-V

## Packaging quantities

Cerenia tablets are supplied in blister packs with four tablets per pack.

## Further information

Nil.

## Marketing Authorisation Number

EU/2/06/062/001-004

## Significant changes

### GTIN

GTIN description: 4 x 16 mg:

GTIN: 05013457079630

GTIN description: 4 x 24 mg:

GTIN: 05013457079647

GTIN description: 4 x 60 mg:

GTIN: 05013457079678

GTIN description: 4 x 160 mg:

GTIN: 05013457079654

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