

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box / Tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cerenia 160 mg tablets for dogs
maropitant

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 160 mg maropitant as maropitant citrate monohydrate.
The tablets also contain Sunset Yellow (E110) as a colorant.

3. PHARMACEUTICAL FORM

Tablets

4. PACKAGE SIZE

4 tablets

5. TARGET SPECIES

Dogs

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
It is recommended to initiate treatment of emesis with Cerenia solution for injection.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/5010

17. MANUFACTURER’S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER / Tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cerenia 160 mg tablets for dogs
maropitant

2. NAME OF MARKETING AUTHORISATION HOLDER

Zoetis
(Logo)

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

**PACKAGE LEAFLET:
Cerenia tablets for dogs**

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
Belgium

Manufacturer responsible for batch release:

FAREVA AMBOISE
Zone Industrielle,
29 route des Industries
37530 Pocé-sur-Cisse
FRANCE

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cerenia 16 mg tablets for dogs
Cerenia 24 mg tablets for dogs
Cerenia 60 mg tablets for dogs
Cerenia 160 mg tablets for dogs

maropitant

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

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 allowing the tablet to be halved, with the letters "MPT" and figures denoting the quantity of maropitant on one side, the reverse side is blank.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

Administering Cerenia on a completely empty stomach may cause your dog to vomit. Giving your dog a light meal or snack before administering the tablet could help preventing this effect. Prolonged fasting before administration should be avoided.

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.

Neurological disorders such as ataxia, convulsion/seizure or muscle tremor have been reported in very rare cases.

Lethargy has been reported in very rare cases.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use.

For prevention of nausea induced by chemotherapy and treatment and prevention of vomiting (except motion sickness), only for dogs 8 weeks of age or older

To treat and/or prevent vomiting except motion sickness, 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 to treat or prevent vomiting either as tablets or as solution for injection administered once daily. Cerenia solution for injection may be administered for up to five days and Cerenia tablets for up to fourteen days.

Prevention of nausea induced by chemotherapy Treatment and prevention of vomiting (except motion sickness)			
Dog body weight (kg)	Number of tablets		
	16 mg	24 mg	60 mg
3.0–4.0*	$\frac{1}{2}$		
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, only for dogs 16 weeks of age or older

To prevent vomiting induced by motion sickness, 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 body weight (kg)	Number of tablets			
	16 mg	24 mg	60 mg	160 mg
1.0-1.5		$\frac{1}{2}$		
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				$\frac{1}{2}$
10.1–15.0			2	
15.1–20.0				1
20.1–30.0				1½
30.1–40.0				2
40.1–60.0				3

9. ADVICE ON CORRECT ADMINISTRATION

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.

For motion sickness 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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE CONDITIONS

Keep out of the sight and reach of children.

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister after EXP.

12. SPECIAL WARNINGS

Special warnings for each target species:

Vomiting can be associated with serious, severely debilitating conditions and the cause should be investigated. Products such as Cerenia should be used in conjunction with other supportive measures such as dietary control and fluid replacement therapy, as recommended by your veterinary surgeon. The safety of maropitant during treatment beyond 5 days has not been explored in the target population (i.e. young dogs suffering from viral enteritis). In case treatment for a longer period than 5 days is regarded as necessary, 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 should be implemented during long term treatment.

Special precautions for use in animals:

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. The responsible veterinarian should make a benefit-risk assessment before using Cerenia in dogs under 8 or 16 weeks of age, respectively, or in pregnant or lactating bitches.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

Cerenia tablets are supplied in blister packs with four tablets per pack. Not all pack sizes may be marketed.

Approved 26 August 2022

