PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cerenia 16 mg tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains 16 mg maropitant as maropitant citrate monohydrate.

3. PACKAGE SIZE

4 tablets.

4. TARGET SPECIES

Dogs

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Keep the blister in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5009

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cerenia

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

16 mg
maropitant

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. {mm/yyyy}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis
(Logo)

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. 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

2. COMPOSITION

Each tablet contains 16 mg, 24 mg, 60 mg or 160 mg maropitant as maropitant citrate monohydrate.
The tablets also contain 0.075 % w/w 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.

3. TARGET SPECIES

Dogs.

4. INDICATIONS FOR USE

- 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. SPECIAL WARNING(S)

Special warnings:
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.

Special precautions for safe use in the target species:
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.

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.

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.

Interaction with other medicinal products and other forms of interaction:
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.

Overdose:
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 water faeces have been observed when the product has been administered at doses in excess of 20 mg/kg.

7. ADVERSE EVENTS

Dogs:

Common (1 to 10 animals / 100 animals treated)
Vomiting[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports)
Neurological disorder (e.g. ataxia, convulsion, seizure, muscle tremor) Lethargy

[1]Observed pre-travel, usually within two hours of dosing.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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*	**½**		
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		½		
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				½
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 PRECAUTIONS

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 outer cardboard box.

Do not use this veterinary medicinal product after the expiry date which is stated on the blister after Exp. The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

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

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5009
Vm 42058/5010
Vm 42058/5011
Vm 42058/5012

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

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

June 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. CONTACT DETAILS

Marketing authorisation holder:
Zoetis Belgium
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

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Zoetis Belgium
Mercuriusstraat 20
BE-1930 Zaventem
Tél/Tel: +32 (0) 800 99 189

Република България
Zoetis Belgium
Rue Laid Burniat 1
1348 Louvain-La-Neuve
Белгия
Тел: +359 888 51 30 30

Česká republika
Zoetis Česká republika, s.r.o.
náměstí 14. října 642/17
CZ 150 00 Praha
Tel: +420 257 101 111

Danmark
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Tlf: +45 70 20 73 05
adr.scandinavia@zoetis.com

Lietuva
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belgija
Tel: +370 610 05088

Luxembourg/Luxemburg
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belsch
Tél/Tel: +32 (2) 746 80 11

Magyarország
Zoetis Hungary Kft.
Csörsz u. 41.
HU-1124 Budapest
Tel.: +36 1 224 5200

Malta
Agrimed Limited
Mdina Road, Zebbug ZBG 9016,
MT
Tel: +356 21 465 797

Deutschland
Zoetis Deutschland GmbH
Schellingstr. 1
DE-10785 Berlin
Tel: +49 30 2020 0049
tierarzneimittelsicherheit@zoetis.com

Eesti
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belgia
Tel: +370 610 05088

Κύπρος
Zoetis Hellas S.A.
Φραγκοκκλησιάς 7, Μαρούσι
15125, Αττική
Ελλάδα
Τηλ: +30 210 6791900

España
Zoetis Spain, S.L.
Parque Empresarial Vía Norte Edificio nº1,
c/ Quintanavides nº13
ES-28050 Madrid
Tel: +34 91 4191900

France
Zoetis France
10 rue Raymond David
FR-92240 Malakoff
Tél: +33 (0)800 73 00 65

Hrvatska
Zoetis B.V.
Podružnica Zagreb za promidžbu
Petra Hektorovića 2
HR-10000 Zagreb
Tel: +385 1 6441 462

Nederland
Zoetis B.V.
Rivium Westlaan 74
NL-2909 LD Capelle aan den IJssel
Tel: +31 (0)10 714 0900

Norge
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Danmark
Tlf: +47 23 29 86 80
adr.scandinavia@zoetis.com

Österreich
Zoetis Österreich GmbH
Floridsdorfer Hauptstr. 1
AT-1210 Wien
Tel: +43 (0)1 2701100 100

Polska
Zoetis Polska Sp. z o.o.
ul. Postępu 17B
PL - 02-676 Warszawa
Tel.: +48 22 2234800

Portugal
Zoetis Portugal Lda.
Lagoas Park, Edifício 10
PT-2740-271 Porto Salvo
Tel: +351 21 042 72 00

România
Zoetis România S.R.L.
Expo Business Park, 54A Aviator Popișteanu, Clădirea 2, Etaj 1-3, Sector 1,
București, 012095 - RO
Tel: +40785019479

Ireland
Zoetis Belgium S.A. (Irish Branch)
2nd Floor, Building 10, Cherrywood
Business Park, Loughlinstown,
Co. Dublin,
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800

Ísland
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 København
Danmörku
Sími: +45 70 20 73 05
adr.scandinavia@zoetis.com

Italia
Zoetis Italia S.r.l.
Via Andrea Doria 41M,
IT-00192 Roma
Tel: +39 06 3366 8111

Ελλάδα
Zoetis Hellas S.A.
Φραγκοκκλησιάς 7, Μαρούσι
EL-15125 Αττική
Τηλ: +30 210 6791900

Latvija
Zoetis Belgium
Mercuriusstraat 20
1930 Zaventem
Belgija
Tel: +370 610 05088

Slovenija
Zoetis B.V.
Podružnica Zagreb za promidžbu
Petra Hektorovića 2,
10000 Zagreb,
Hrvaška
Tel: +385 1 6441 462

Slovenská republika
Zoetis Česká republika, s.r.o.
náměstí 14. října 642/17
150 00 Praha
Česká republika
Tel: +420 257 101 111

Suomi/Finland
Zoetis Finland Oy
Bulevardi 21 / SPACES
FI-00180 Helsinki/Helsingfors
Suomi/Finland
Puh/Tel: +358 10 336 7000
laaketurva@zoetis.com

Sverige
Zoetis Animal Health ApS
Øster Alle 48
DK-2100 Köpenhamn
Danmark
Tel: +46 (0) 76 760 0677
adr.scandinavia@zoetis.com

United Kingdom (Northern Ireland)
Zoetis Belgium S.A. (Irish Branch)
2nd Floor, Building 10, Cherrywood
Business Park, Loughlinstown,
Co. Dublin,
IE – Dublin D18 T3Y1
Tel: +353 (0) 1 256 9800

Approved 20 February 2024