PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cerenia 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

10 mg/ml maropitant (as maropitant citrate monohydrate).
3.3 mg/ml metacresol (as preservative)

3. PACKAGE SIZE

20 ml

4. TARGET SPECIES

Dogs and cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Subcutaneous or intravenous use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 60 days.
Once broached, use by:

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial 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
First Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5008

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

In case of accidental self-injection seek medical advice immediately and show the package leaflet or the label to the physician.

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 SMALL IMMEDIATE PACKAGING UNITS {Glass vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cerenia

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

10 mg/ml

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 60 days.

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. 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 10 mg/ml solution for injection for dogs and cats

2. COMPOSITION

The solution for injection contains 10 mg maropitant per ml as maropitant citrate monohydrate as a clear, colourless to light yellow solution.
It also contains metacresol (as preservative) 3.3 mg/ml.

3. TARGET SPECIES

Dogs and cats.

4. INDICATIONS FOR USE

Dogs

- For the treatment and prevention of nausea induced by chemotherapy.
- For the prevention of vomiting except that induced by motion sickness.
- For the treatment of vomiting, in combination with other supportive measures.
- For the prevention of perioperative nausea and vomiting and improvement in recovery from general anaesthesia after use of the μ-opiate receptor agonist morphine.

Cats

- For the prevention of vomiting and the reduction of nausea, except that induced by motion sickness.
- For the treatment of vomiting, in combination with other supportive measures.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNING(S)

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

Good veterinary practice indicates that antiemetics should be used in conjunction with other veterinary and supportive measures such as dietary control and fluid replacement therapy while addressing the underlying causes of the vomiting.

The use of Cerenia solution for injection against vomiting due to motion sickness is not recommended.

Dogs:
Although Cerenia has been demonstrated to be effective in both the treatment and prevention of emesis induced by chemotherapy, it was found more efficacious if used preventively. Therefore, it is recommended to administer the antiemetic prior to administration of the chemotherapeutic agent.

Cats:
The efficacy of Cerenia in reduction of nausea was demonstrated in studies using a model (xylazine-induced nausea).

Special precautions for safe use in the target species:
The safety of Cerenia has not been established in dogs less than 8 weeks of age, or in cats less than 16 weeks of age, and in pregnant or lactating dogs and cats. The responsible veterinarian should make a benefit-risk assessment before using Cerenia in dogs less than 8 weeks of age, or in cats less than 16 weeks of age, or in pregnant or lactating bitches and cats.

Maropitant is metabolised in the liver and therefore should be used with caution in dogs and cats with liver disease. Cerenia should be used with caution in animals suffering from or with predisposition for heart diseases.

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 self-injection seek medical advice immediately and show the package leaflet or the label to the physician. Maropitant has been shown to be a potential eye irritant, and in the case of accidental eye exposure, flush the eyes with plenty of water and seek medical attention.

Pregnancy and lactation:
Use only according to the benefit-risk assessment by the responsible veterinarian, because conclusive reproductive toxicity studies have not been conducted in any animal species.

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 medicines.

Overdose:
Apart from transient reactions at the injection site following subcutaneous administration, Cerenia solution for injection was well tolerated in dogs and young cats injected daily with up to 5 mg/kg bodyweight (5 times the recommended dose)

for 15 consecutive days (3-times the recommended duration of administration). No data have been presented on overdoses in adult cats.

Major incompatibilities:
Cerenia must not be mixed with other veterinary medicinal products in the same syringe as its compatibility with other products has not been tested.

7. ADVERSE EVENTS

Dogs and cats:

Very common (>1 animal / 10 animals treated):
Injection site pain[1,2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylactic-type reaction (e.g. allergic oedema, urticaria, collapse NOS, dyspnoea, pale mucous membranes) Lethargy Neurological disorder (e.g. ataxia, convulsion, seizure, muscle tremor)

[1] When injected subcutaneously.
[2] A moderate to severe response can be observed in approximately one third of cats.

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 subcutaneous or intravenous use in dogs and cats.

Cerenia solution for injection should be injected subcutaneously or intravenously, once daily, at a dose of 1 mg/kg bodyweight (1 ml/10 kg bodyweight). Treatment may be repeated for up to five consecutive days. Intravenous administration of Cerenia should be given as a single bolus without mixing the product with any other fluids.

In dogs, Cerenia solution for injection can be used to treat or prevent vomiting once daily for up to 5 days.

9. ADVICE ON CORRECT ADMINISTRATION

To prevent vomiting, Cerenia solution for injection should be administered more than 1 hour in advance. The effect duration is approximately 24 h and therefore treatment

can be given the night before administration of an agent that may cause emesis e.g. chemotherapy.

Due to the frequent occurrence of transient pain during subcutaneous injection, appropriate animal restraining measures may have to be applied. Injecting the product at refrigerated temperature may reduce pain at injection.

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.
Do not use this veterinary medicinal product after the expiry date which is stated on the label of the vial after Exp.
The expiry date refers to the last day of that month.
Shelf life after first opening the vial: 60 days.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater or household waste.

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 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 42058/5008

Cerenia 10 mg/ml solution for injection for dogs and cats is available in 20 ml amber glass vials. Each cardboard box contains 1 vial.

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:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. de Camprodón, s/n°
Finca La Riba
Vall de Bianya
Gerona 17813
Spain

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
BeļģijaTel: +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

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