LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box / Solution for injection

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cerenia 10 mg/ml solution for injection for dogs and cats
maropitant

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml of solution contains 10 mg maropitant (as maropitant citrate monohydrate).

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

SC, IV
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. 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.

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by:……..

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/5008

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial / Solution for injection

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cerenia 10 mg/ml injection for dogs and cats
maropitant

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

10 mg/ml

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

20 ml

4. ROUTE(S) OF ADMINISTRATION

SC, IV

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}
Once broached, use within 60 days.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET

PACKAGE LEAFLET:
Cerenia 10 mg/ml solution for injection for dogs and cats

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

or

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cerenia 10 mg/ml solution for injection for dogs and cats
maropitant

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

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).

4. INDICATION(S)

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. ADVERSE REACTIONS

Pain at injection site may occur when injected subcutaneously.

In cats, moderate to severe response to injection is very commonly observed (in approximately one third of cats).

Anaphylactic type reactions (allergic oedema, urticaria, erythema, collapse, dyspnoea, pale mucous membranes) may occur in very rare cases.

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 and cats.

8. DOSAGE FOR EACH SPECIES, ROUTES 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 CONDITIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Shelf life after first opening the vial: 60 days. Do not use this veterinary medicinal product after the expiry date which is stated on the label of the vial 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.

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.

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

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

Special precautions for use in animals:
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.

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 drugs.

Overdose (symptoms, emergency procedures, antidotes):
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 (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.

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.

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

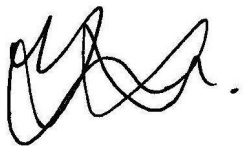
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH PACKAGE LEAFLET WAS LAST APPROVED

August 2022

15. OTHER INFORMATION

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



Approved: 02 September 2022