PARTICULARS TO APPEAR ON THE OUTER PACKAGE
{Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arocenia 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES AND OTHER SUBSTANCES

Each ml contains 10 mg of maropitant.

3. PACKAGE SIZE

20 ml

4. TARGET SPECIES

Dogs, cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

s.c.
i.v.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp.

Once broached use within 60 days.

9. SPECIAL STORAGE PRECAUTIONS

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 OF THE MARKETING AUTHORISATION HOLDER

KRKA

14. MARKETING AUTHORISATION NUMBERS

Vm 01656/5038

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

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

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

{Label on vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arocenia

2. QUANTITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 mg/ml maropitant

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp.

5. ROUTE(S) OF ADMINISTRATION

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

KRKA

PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Arocenia 10 mg/ml solution for injection for dogs and cats

2. COMPOSITION

Each ml contains:
Active substance: Maropitant (as maropitant citrate monohydrate) 10 mg
Excipient: Benzyl alcohol 11.1 mg

Clear, colourless to light yellow or to slightly brown solution.

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 WARNINGS

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 the veterinary medicinal product against vomiting due to motion sickness is not recommended.

Dogs:

Although maropitant 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 maropitant 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 the veterinary medicinal product 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. Use only according to the benefit-risk assessment by the responsible veterinarian.

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

The veterinary medicinal product should be used with caution in animals suffering from or with predisposition for cardiac diseases as maropitant has affinity to Ca- and K-ion channels. Increases of approximately 10% in the QT interval of the ECG were observed in a study on healthy beagle dogs administered 8 mg/kg orally; however, such an increase is unlikely to be of clinical significance.

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

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

Maropitant is a neurokinin-1 (NK1) receptor antagonist that acts in the central nervous system. The veterinary medicinal product may therefore cause nausea, dizziness and drowsiness in case of accidental self-injection. If accidental self-injection occurs, seek medical advice immediately and show the package leaflet or the label to the physician.

Due to the content of benzyl alcohol the veterinary medicinal product may cause mild local irritation. Skin contact should therefore be avoided. In case of accidental exposure, wash affected skin area with plenty of water.

The veterinary medicinal product may cause skin sensitisation. People with known hypersensitivity to maropitant or to any of the excipients should administer the veterinary medicinal product with caution. If you develop symptoms such as a skin rash after accidental exposure, seek medical advice and show the physician this warning.

The veterinary medicinal product may cause eye irritation. Eye contact should be avoided. In case of accidental eye exposure, flush the eyes with plenty of water and seek medical attention.
Wash hands after use.

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:
The veterinary medicinal product 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:
Apart from transient reactions at the injection site following subcutaneous administration, maropitant 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.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. ADVERSE EVENTS

Dogs, 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 (allergic oedema, urticaria, erythema, collapse, dyspnoea, pale mucous membrane). Lethargy. Neurological disorders (ataxia, convulsion/seizure or muscle tremor).

[1] When injected subcutaneously to cat: moderate to severe response to injection (in approximately one third of cats).
[2] When injected subcutaneously to dog.

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 {https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine}.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

For subcutaneous or intravenous use in dogs and cats.

The veterinary medicinal product should be injected subcutaneously or intravenously, once daily, at a dose of 1 mg/kg bodyweight (1 ml/10 kg bodyweight) for up to 5 consecutive days. Intravenous administration of the veterinary medicinal product should be given as a single bolus without mixing the veterinary medicinal product with any other fluids.

9. ADVICE ON CORRECT ADMINISTRATION

To prevent vomiting, the veterinary medicinal product 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.

As the pharmacokinetic variation is large and maropitant accumulates in the body after once daily repeated administration, lower doses than recommended might be sufficient in some individuals and when repeating the dose.

For administration by subcutaneous injection, see also “Special precautions for safe use in the target species” (section 6).

The cap may be safely punctured up to 40 times. It is recommended that a draw-off needle be used to reduce the number of times the septum is punctured.

10. WITHDRAWAL PERIODS

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 after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 60 days.

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 products should be disposed of in accordance with local requirements.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

POM-V

For animal treatment only.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 01656/5038

Cardboard box containing 1 vial of 20 ml.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia

Manufacturer responsible for batch release:

KRKA, d.d., Novo mesto, Šmarješka cesta 6, 8501 Novo mesto, Slovenia
TAD Pharma GmbH, Heinz-Lohmann-Straße 5, 27472 Cuxhaven, Germany

Local representatives and contact details to report suspected adverse reactions:

KRKA UK Ltd
United Kingdom
Tel: 02071 646 156
Email: info.uk@krka.biz

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. OTHER INFORMATION

Approved 20 December 2024
Gavin Hall