SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bonqat 50 mg/ml oral solution for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Pregabalin 50 mg

Excipient:
Sodium benzoate (E211) 2 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.

Clear, colourless to slightly reddish solution

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

Alleviation of acute anxiety and fear associated with transportation and veterinary visits.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

The safety of the veterinary medicinal product has not been established in cats weighing less than 2 kg, younger than 5 months and older than 15 years. Use only according to the benefit-risk assessment by the responsible veterinarian.

The safety of the veterinary medicinal product has only been established in healthy cats or those with mild systemic illness. It has not been established in animals with moderate or severe systemic disease e.g. moderate to severe renal, liver, or cardiovascular disease. Use only according to the benefit-risk assessment by the responsible veterinarian.

Always assess the cat's health status before prescribing the veterinary medicinal product.

The veterinary medicinal product may cause slight reduction in heart rate, respiratory rate and body temperature. As a reduction of body temperature can occur after the administration, the treated animal should be kept at a suitable ambient temperature. Monitor the cat carefully for any symptoms of respiratory depression and sedation when a CNS depressant is used concomitantly with pregabalin.

The prescribing veterinarian should advise the owner to always inform the attending veterinarian if the veterinary medicinal product has been administered to the cat prior to the veterinary visit.

If the cat spits part of the dose, vomits after treatment, or in case of hypersalivation, do not give another dose.

The effect of the veterinary medicinal product can last approximately 7 hours. In case the cat seems drowsy or shows other signs of exaggerated effects after treatment administration, keep the cat indoors and do not offer water or feed until the cat has fully recovered.

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

Exposure to pregabalin may cause adverse effects such as dizziness, tiredness, ataxia, blurred vision and headache.

Avoid skin, eye or mucosal contact. Thoroughly wash hands immediately after administration of the veterinary medicinal product.

In case of accidental eye or mucosal contact, flush with water. Seek medical advice if symptoms (dizziness, tiredness, ataxia or blurred vision) occur.

In case of skin contact, wash with soap and water. Remove contaminated clothing.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive as tiredness may occur.

4.6 Adverse reactions (frequency and seriousness)

Signs of sedation (characterised by lethargy, proprioception abnormality and ataxia) and emesis have been observed commonly in clinical studies. Muscle tremor, mydriasis, anorexia, weight loss and leucopenia have been reported uncommonly in clinical studies. Salivation has been reported rarely in clinical studies. Typically, clinical signs are mild and transient.

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).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats and rabbits have shown evidence of embryofoetotoxic and maternotoxic effects when pregabalin is administered repeatedly at high doses (≥ 1 250 mg/kg/day). The safety of the veterinary medicinal product has not been established in breeding animals or during pregnancy and lactation in the target species. Use only according to the benefit-risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

The use of other central nervous system depressants is expected to potentiate the effects of pregabalin and therefore an appropriate dose adjustment should be made.

4.9 Amounts to be administered and administration route

Oral use.

The veterinary medicinal product is administered orally as a single dose of 5 mg/kg bodyweight (0.1 ml/kg bw) approximately 1.5 hours before the start of the transportation/planned veterinary visit.

The veterinary medicinal product can be administered either directly into the mouth or mixed with a small amount of food. Large amounts of food may delay the onset of effect.

Use the oral syringe provided in the package for administration of the veterinary medicinal product.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Safety following repeated administration for 6 consecutive days and at up to 5 times the recommended treatment dose was investigated in an overdose study.
Signs related to motor coordination (abnormal gait, limited usage of hind limbs/paws, uncoordinated behaviour, ataxia), somnolence (decreased activity, closed eyes, lying

on side, dilated pupils, decreased body temperature and depression), vomiting and salivation were observed at greater frequency, severity and duration of the signs with doses of 15 mg/kg and 25 mg/kg than that observed at the recommended dose rate of 5 mg/kg bodyweight. Loss of consciousness was noted in one out of eight cats at 25 mg/kg.

If decrease in body temperature occurs, the cat should be kept warm.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Nervous system, other antiepileptics
ATC vet code: QN03AX16

5.1 Pharmacodynamic properties

Pregabalin binds to the auxiliary subunit (alpha2-delta protein) of voltage-gated calcium channels in the central nervous system thereby reducing the release of various neurotransmitters (glutamate and monoaminergic neurotransmitters) and producing its anxiolytic effect.

5.2 Pharmacokinetic particulars

Absorption
Pregabalin is rapidly absorbed after oral administration in cats. The C_{max} in plasma was 10.1 µg/ml and occurred at 0.5–1.0 hours after administration of 5 mg/kg bodyweight into the mouth of cats in fasted state. The area under plasma concentration-time curve ($AUC_{0\text{-}24h}$) in fasted state was 129 µg*h/ml. The mean absolute oral bioavailability of pregabalin was 94.3%. After re-dosing of 5 mg/kg at 24 hours, the exposure, in terms of C_{max}, $AUC_{0\text{-}24h}$, and $t_{1/2}$, was comparable with the exposure following single dosing. No significant differences were noted in overall absorption, expressed as plasma C_{max} and AUC, after administration of pregabalin into the mouth under different feeding regimes.

Distribution
Pregabalin has a relatively large volume of distribution. After intravenous bolus administration, the volume of distribution at the steady state (V_{ss}) was 0.4 l/kg. Pregabalin is not known to bind to plasma proteins in mice, rats, monkeys or humans. This has not been studied in cats.

Metabolism and excretion
Pregabalin is quite slowly eliminated from the body of cats. Total plasma clearance was 0.03 l/h/kg. The mean half-life of elimination from circulation was 12.3 hours after intravenous administration of 2.5 mg/kg and 14.7 hours after oral administration of 5 mg/kg.

Elimination of the parent compound as well as the methylation metabolite from circulation occurs almost exclusively by renal excretion in rats, monkeys and

humans. In dogs, approximately 45% of the pregabalin dose is excreted in urine as N-methyl metabolite. This has not been studied in cats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate (E211)
Ethyl maltol
Hydrochloric acid, dilute (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Purified water

6.2 Major incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging (removal of the cap): 6 months.
Once opened the bottle should be stored in a refrigerator but may be stored for short periods of time (up to 1 month in total) at or below 25°C.

6.4 Special precautions for storage

Store in a refrigerator (2°C–8°C).

6.5 Nature and composition of immediate packaging

A clear Type III glass bottle containing 2 ml of product. The bottle is closed with a polypropylene child-resistant closure and a high-density polyethylene liner integrated with a low-density polyethylene adapter. A 1 ml low-density polyethylene oral syringe is included in the box. The syringe is graduated in increments of 0.1 ml.

Pack size: 1 bottle and a syringe in a cardboard box

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

8. MARKETING AUTHORISATION NUMBER

Vm 06043/5003

9. DATE OF FIRST AUTHORISATION

16 July 2021

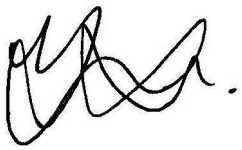
10. DATE OF REVISION OF THE TEXT

June 2023

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.



Approved: 07 June 2023