

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

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Sodium benzoate (E211)	2 mg
Ethyl maltol	
Hydrochloric acid, dilute (for pH adjustment)	
Sodium hydroxide (for pH adjustment)	
Purified water	

Clear, colourless to slightly reddish solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats

3.2 Indications for use for each target species

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

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats:

Common (1 to 10 animals / 100 animals treated):	Emesis Ataxia, Sedation, Proprioception abnormality Lethargy
Uncommon (1 to 10 animals / 1 000 animals treated):	Leucopenia Muscle tremor, Mydriasis Anorexia, Weight loss
Rare (1 to 10 animals / 10 000 animals treated):	Salivation

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laboratory studies in rats and rabbits have shown evidence of embryofetotoxic and maternotoxic effects when pregabalin is administered repeatedly at high doses ($\geq 1\,250$ 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.

3.8 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.

3.9 Administration routes and dosage

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.

3.10 Symptoms of Overdose (and where applicable, emergency procedures, antidotes)

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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal period

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN02BF02

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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_{0-24h}) 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_{0-24h} , 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf life after first opening the immediate packaging: 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.

5.3 Special precautions for storage

Store in a refrigerator (2 °C–8 °C).

5.4 Nature and composition of immediate packaging

A clear Type III glass bottle containing 2 ml of veterinary medicinal 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.

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

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Orion Corporation

7. MARKETING AUTHORISATION NUMBER

Vm 06043/5003

8. DATE OF FIRST AUTHORISATION

25 June 2021

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

May 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 11 August 2025