ANNEX I

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 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_{0-24h}) 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.

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: 2 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(S)

EU/2/21/273/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13 July 2021

10. DATE OF REVISION OF THE TEXT

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.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release

Orion Corporation Orion Pharma
Tengströminkatu 8
FI-20360 Turku
Finland

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bonqat 50 mg/ml oral solution for cats
pregabalin

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains: 50 mg pregabalin.

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

2 ml
1 oral syringe

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Once opened use within 6 months.

11. SPECIAL STORAGE CONDITIONS

Store in a refrigerator.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

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

Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/21/273/001

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE (GLASS)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bonqat 50 mg/ml oral solution for cats
pregabalin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

50 mg/ml

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

2 ml

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Once opened use within 6 months.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Bonqat 50 mg/ml oral solution for 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:
Orion Corporation
Orionintie 1
FI-02200 Espoo
Finland

Manufacturer responsible for batch release:
Orion Corporation Orion Pharma
Tengströminkatu 8
FI-20360 Turku
Finland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Bonqat 50 mg/ml oral solution for cats
pregabalin

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

Each ml contains:

Active substance:
Pregabalin 50 mg

Excipient:
Sodium benzoate (E211) 2 mg

Clear, colourless solution.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

Signs of sedation (characterised by tiredness, difficulties in perception of the position and movement of the body, and problems with balance) and vomiting have been observed commonly in clinical studies. Muscle tremor, dilatated pupils, loss of appetite, weight loss and reduced number of white blood cells 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).

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

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The recommended dose is 0.1 ml/kg bodyweight. Administer the product orally.

9. ADVICE ON CORRECT ADMINISTRATION

Give Bonqat 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 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.

See the detailed instructions for administration at the end of this leaflet.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store in a refrigerator (2°C–8°C).

Shelf life after first opening the bottle in a refrigerator: 6 months. Once opened the bottle should be stored in a refrigerator but may be stored for short periods of time (up to to 1 month in total) at or below 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special precautions for use in cats:

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

The cat's health status needs always to be assessed by the veterinarian before prescribing the veterinary medicinal product.

The veterinary medicinal product may cause slight decrease in heart rate, respiratory rate and body temperature. As a decrease 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 sleepiness and respiratory depression if the veterinarian informs that another medicine causing central nervous system depression has been used concomitantly with the veterinary medicinal product.

The animal owner should be advised by the prescribing veterinarian 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 excessive salivation, 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 the veterinary medicinal product may cause adverse effects such as dizziness, tiredness, balance problems, 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, balance problems 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.

Pregnancy and lactation:
Laboratory studies in rats and rabbits have shown evidence of harmful effects during pregnancy when pregabalin is administered repeatedly at very high doses (≥ 250-fold the recommended dose for cats). The safety of the veterinary medicinal product has not been established during pregnancy and lactation in cats. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interactions
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 by the prescribing veterinarian.

Overdose (symptoms, 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. Overdose (3- and 5-fold higher than the recommended dose) can cause signs related to problems with balance, tiredness, vomiting and salivation at greater frequency, severity and duration than the adverse reactions observed at the recommended dose. On rare occasions loss of consciousness can be seen at the 5-fold dose.
If decrease in body temperature occurs, the cat should be kept warm.

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

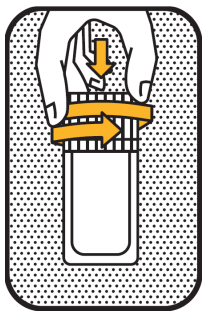
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

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

15. OTHER INFORMATION

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

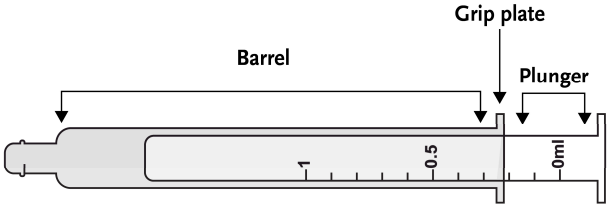
INSTRUCTIONS FOR ADMINISTRATION:

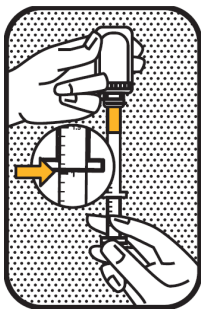


1. REMOVE CAP
Remove the cap from the bottle (press down and twist). Save the cap for reclosure.

2. CONNECT SYRINGE

Push the plunger to the bottom of the syringe barrel to squeeze all the air out of the syringe. Push the syringe tightly into the adapter located at the top of the bottle. Use only the syringe provided with the product.





3. SELECT DOSE

Turn the bottle with the syringe in place upside down. Pull the plunger out until the black line of correct dose (ml) (prescribed by your veterinarian) can be seen under the grip plate of the syringe barrel.

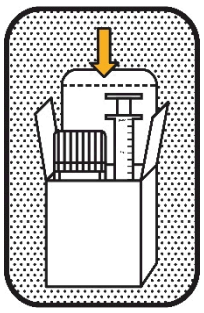
If the cat weighs more than 10 kg, the total dose will need to be calculated and given in two separate doses as the syringe holds maximally only 1.0 ml of solution.

Don't leave the filled dosing syringe unattended while preparing the cat for administration.

4. ADMINISTER DOSE

Gently place the syringe in the mouth of the cat and administer the dose to the base of the tongue by gradually pressing the plunger until the syringe is empty.

If the dose cannot be given directly into mouth the product can be mixed with small amount of cat's favourite food. Do not leave additional food available for the cat after the dose has been administered as extra food may delay the onset of effect .



5. BACK TO PACKAGE

Replace the cap and rinse the syringe with water after use. Return the syringe and bottle to the cardboard box and store them in the refrigerator.

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

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