ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eluracat 20 mg/ml oral solution for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Capromorelin 15.4 mg equivalent to 20 mg capromorelin tartrate

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Sodium methyl parahydroxybenzoate (E 219)	1.5 mg
Sodium propyl parahydroxybenzoate (E 217)	0.25 mg
Sodium chloride	
Citric acid	
Sucralose	
Vanillin	
Povidone (K-90)	
Glycerol	
Maltitol, liquid	
Magnasweet 110 (glycyrrhizic acid, monoammonium glycyrrhizinate)	
Purified water	

Clear, colourless to yellowish or orange solution.

3. CLINICAL INFORMATION

3.1 Target species

Cats

3.2 Indications for use for each target species

For body weight gain in cats experiencing poor appetite or unintended weight loss resulting from chronic medical conditions (see section 4.2).

3.3 Contraindications

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

3.4 Special warnings

This veterinary medicinal product does not treat the underlying chronic medical conditions but is intended to provide supportive therapy.

The efficacy in cats less than 6 years old or with less than 2 kg body weight has not been evaluated.

The efficacy of the veterinary medicinal product has not been established for more than 90 days. Therefore, when the treatment is administered for a longer duration, the response to treatment should be monitored.

3.5 Special precautions for use

Special precautions for safe use in the target species:

The veterinary medicinal product has been shown to increase serum glucose levels in cats, with highly variable effects on individual cats. However, in non-diabetic cats homeostatic mechanisms adapt to maintain blood glucose levels within normal ranges after a few days. Use in cats with diabetes mellitus has not been evaluated. In cases of diabetes mellitus, use only according to the benefit/risk assessment by the responsible veterinarian.

Use with caution in cats with hypotension as the veterinary medicinal product caused decreased heart rate and blood pressure for up to 4 hours following dose administration to healthy cats. These effects were reversed by human interaction followed by feeding of the cat.

Use with caution in cats with hypersomatotropism (acromegaly).

Use with caution in cats with hepatic dysfunction as capromorelin is metabolised in the liver.

The safety in cats less than 10 months old or with less than 2 kg body weight has not been evaluated.

The safety of the veterinary medicinal product for a treatment period of more than 90 days in cats with chronic medical conditions has not been evaluated. Therefore, when the treatment is administered for a longer duration, cats should be monitored.

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

Ingestion by children may cause mild and reversible signs of abdominal pain, lethargy, lightheadedness, palpitation, low back pain, feeling warm and increased perspiration. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

This veterinary medicinal product contains parabens and povidone, which may cause allergic reactions. People with known hypersensitivity to these substances should administer the veterinary medicinal product with caution.

This veterinary medicinal product may cause eye and skin irritation. Contact with the eyes, skin and mucous membranes should be avoided. Wash hands after use. In case of accidental eye or skin contact, rinse the affected area immediately with plenty of fresh water. If irritation persists, seek medical advice and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats

Very common (>1 animal / 10 animals treated):	Hypersalivation[1]
Common (1 to 10 animals / 100 animals treated):	Diarrhoea, Vomiting Anaemia Skin lesions (on the mouth and chin) Dehydration, Lethargy

[1] At the time of dosing and resolved within a few minutes.

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 the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during reproduction, pregnancy and lactation in the target species. Laboratory studies in rats have shown evidence of teratogenic effects. Do not use in breeding, pregnant and lactating cats.

3.8 Interaction with other medicinal products and other forms of interaction

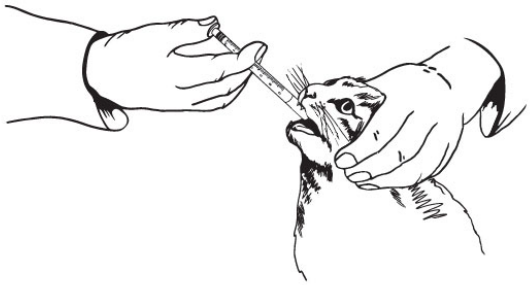
None known.

3.9 Administration routes and dosage

Oral use.

The recommended dose is 2 mg/kg body weight which is equivalent to 0.1 ml/kg body weight. The veterinary medicinal product is to be administered once daily directly into the mouth.

To administer the veterinary medicinal product:
- Remove the cap, insert the dosing syringe, invert the bottle, withdraw the appropriate amount of solution using a ml scale syringe.
- Return the bottle to the upright position, remove the syringe, replace the cap tightly.
- Administer the solution into the cat's mouth.
- Rinse the syringe and the plunger with water and leave apart to dry.



Duration of treatment will depend on the response observed to treatment. Long-term administration of the veterinary medicinal product is likely needed as chronic medical conditions tend to be progressive in nature and weight loss is expected to continue if not treated.

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

After administration of the veterinary medicinal product up to 5 times the recommended dose for 6 months to young healthy cats the following adverse reactions were observed: Non-progressive increases in triglyceride levels were noted in male cats. Increase in liver to brain weight ratio was observed and liver vacuolation was noted in two animals (one in the 3x and one in the 5x group). One male cat in the 5x group was observed with hyperglycaemia and glucosuria. Other adverse reactions observed were consistent with those mentioned in section 3.6.

Capromorelin increased serum growth hormone concentrations in healthy cats at a dosage of 6 mg/kg body weight. The effect was highest after the first dose and was attenuated on subsequent days.

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 periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code

QH01AX90

4.2 Pharmacodynamics

Capromorelin is a selective ghrelin receptor agonist. Capromorelin binds to ghrelin receptors in the hypothalamus to stimulate appetite and in the pituitary to stimulate secretion of growth hormone (GH). Increased GH stimulates release of insulin like growth factor 1 (IGF-1) from the liver, which in turn stimulates weight gain.

The clinical effects of capromorelin in cats are a combination of increased food intake and metabolic changes resulting in weight gain.

In healthy cats, capromorelin increased food consumption, body weight and serum IGF-1 concentrations. In cats with chronic kidney disease and ≥ 5 % unintended body weight loss, capromorelin increased body weight by 6.8 % compared to an untreated control group after 55 days of treatment.

4.3 Pharmacokinetics

Binding of capromorelin to cat plasma proteins was moderate (61 %) over the assessed concentration range of 1 ng/ml to 100 ng/ml.

All pharmacokinetic parameters based on intravenous administration were calculated with data from a non-final formulation.

After oral administration, capromorelin was rapidly absorbed in cats with a T_{max} of 0.5 hours (without food) followed with a second larger peak after 2 hours. The mean half-life of capromorelin in serum following intravenous and oral administration is 0.9 and 1.0 hours. Mean systemic clearance is 31.1 ml/min/kg body weight and mean apparent volume of distribution is 1.6 L/kg body weight. The

short half-life can be attributed to the medium systemic clearance coupled with a medium volume of distribution. The mean oral bioavailability of capromorelin in cats was estimated as 34 % at a dose of 3 mg/kg body weight with a non-final formulation. Administration of capromorelin with the entire daily ration compared to fasted cats led to increases in T_{max} (1.3 versus 0.4 hours) and decreases in C_{max} (28 versus 59 ng/ml) and $AUC_{(0\text{-last})}$ (51 versus 83 ng.hour/ml). However, serum IGF-1 concentrations were increased by a similar amount when capromorelin was administered with or without food.

Serum concentrations of capromorelin increase proportionally with increasing dose over the range 1–4 mg/kg body weight as evidenced by an increase in mean C_{max} and AUC and did not accumulate with repeated dosing over 10 days. There was no difference in pharmacokinetic variables between male and female cats. Renal insufficiency in cats had no effect on capromorelin pharmacokinetics.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 3 months

5.3 Special precautions for storage

Do not store above 30 ºC.

5.4 Nature and composition of immediate packaging

HDPE bottles filled with 10 ml and 15 ml.
Each bottle is closed with an LDPE plug-in adapter and tamper proof child resistant closure.

Pack sizes:
Cardboard box with 1 bottle filled with 10 ml and 1 oral ml scale syringe.
Cardboard box with 1 bottle filled with 15 ml and 1 oral ml scale syringe.

Not all pack sizes may be marketed.

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 or household waste.

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

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/23/297/001
EU/2/23/297/002

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 29 June 2023

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

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eluracat 20 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 20 mg capromorelin tartrate.

3. PACKAGE SIZE

10 ml
15 ml
1 oral syringe

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 ºC.

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

Elanco logo

14. MARKETING AUTHORISATION NUMBERS

EU/2/23/297/001
EU/2/23/297/002

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Eluracat

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

20 mg/ml capromorelin tartrate

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once broached use within 3 months.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Eluracat 20 mg/ml oral solution for cats

2. Composition

Each ml contains:

Active substance:
Capromorelin 15.4 mg equivalent to 20 mg capromorelin tartrate

Excipients:
Sodium methyl parahydroxybenzoate (E 219) 1.5 mg
Sodium propyl parahydroxybenzoate (E 217) 0.25 mg

Clear, colourless to yellowish or orange solution.

3. Target species

Cats

4. Indications for use

For body weight gain in cats experiencing poor appetite or unintended weight loss resulting from chronic medical conditions.

5. Contraindications

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

6. Special warnings

Special warnings:
This veterinary medicinal product does not treat the underlying chronic medical conditions but is intended to provide supportive therapy.
The efficacy in cats less than 6 years old or with less than 2 kg body weight has not been evaluated.
The efficacy of the veterinary medicinal product has not been established for more than 90 days. Therefore, when the treatment is administered for a longer duration, the response to treatment should be monitored.

Special precautions for safe use in the target species:
The veterinary medicinal product has been shown to increase serum glucose levels in cats, with highly variable effects on individual cats. However, in non-diabetic cats homeostatic mechanisms adapt to maintain blood glucose levels within normal ranges after a few days. Use in cats with diabetes mellitus has not been evaluated. In cases of diabetes mellitus, use only according to the benefit/risk assessment by the responsible veterinarian.
Use with caution in cats with hypotension as the veterinary medicinal product caused decreased heart rate and blood pressure for up to 4 hours following dose administration to healthy cats. These effects were reversed by human interaction followed by feeding of the cat.

Use with caution in cats with hypersomatotropism (acromegaly).
Use with caution in cats with hepatic dysfunction as capromorelin is metabolised in the liver.
The safety in cats less than 10 months old or with less than 2 kg body weight has not been evaluated.
The safety of the veterinary medicinal product for a treatment period of more than 90 days in cats with chronic medical conditions has not been evaluated. Therefore, when the treatment is administered for a longer duration, cats should be monitored.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Ingestion by children may cause mild and reversible signs of abdominal pain, lethargy, lightheadedness, palpitation, low back pain, feeling warm and increased perspiration. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
This veterinary medicinal product contains parabens and povidone, which may cause allergic reactions. People with known hypersensitivity to these substances should administer the veterinary medicinal product with caution.
This veterinary medicinal product may cause eye and skin irritation. Contact with the eyes, skin and mucous membranes should be avoided. Wash hands after use. In case of accidental eye or skin contact, rinse the affected area immediately with plenty of fresh water. If irritation persists, seek medical advice and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during reproduction, pregnancy and lactation in the target species. Laboratory studies in rats have shown evidence of teratogenic effects. Do not use in breeding, pregnant and lactating cats.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
After administration of the veterinary medicinal product up to 5 times the recommended dose for 6 months to young healthy cats the following adverse reactions were observed: Non-progressive increases in triglyceride levels were noted in male cats. Increase in liver to brain weight ratio was observed and liver vacuolation was noted in two animals (one in the 3x and one in the 5x group). One male cat in the 5x group was observed with hyperglycaemia and glucosuria. Other adverse reactions observed were consistent with those mentioned in the adverse events section of this package leaflet. Capromorelin increased serum growth hormone concentrations in healthy cats at a dosage of 6 mg/kg body weight. The effect was highest after the first dose and was attenuated on subsequent days.

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

7. Adverse events

Cats

Very common (> 1 animal / 10 animals treated):
Drooling[1]
Common (1 to 10 animals / 100 animals treated):
Diarrhoea, Vomiting

Anaemia Skin lesions (on the mouth and chin) Dehydration, Lethargy

[1] At the time of dosing and resolved within a few minutes.

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 using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Oral use.

The recommended dose is 2 mg/kg body weight, which is equivalent to 0.1 ml/kg body weight.

9. Advice on correct administration

The veterinary medicinal product is to be administered once daily directly into the mouth.

To administer the veterinary medicinal product:
- Remove the cap, insert the dosing syringe, invert the bottle, withdraw the appropriate amount of solution using a ml scale syringe.
- Return the bottle to the upright position, remove the syringe, replace the cap tightly.
- Administer the solution into the cat's mouth.
- Rinse the syringe and the plunger with water and leave apart to dry.

Duration of treatment will depend on the response observed to treatment. Long-term administration of the veterinary medicinal product is likely needed as chronic medical conditions tend to be progressive in nature and weight loss is expected to continue if not treated.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30 ºC.

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

Shelf life after first opening the immediate packaging: 3 months.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/23/297/001
EU/2/23/297/002

Pack sizes:
Cardboard box with 1 bottle filled with 10 ml and 1 oral ml scale syringe.
Cardboard box with 1 bottle filled with 15 ml and 1 oral ml scale syringe.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Elanco GmbH, Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany

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Manufacturer responsible for batch release:
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