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 tartrate 20 mg (equivalent to 15.4 mg capromorelin)

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.
Do not use in patients with severe haemodynamic instability such as hypovolaemic shock. See also section 3.5 Special precautions for safe use in the target species.
Do not use in patients with hypersomatotropism (acromegaly).

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, the product should only be used for a period of greater than 90 days following a benefit-risk assessment by the responsible veterinary surgeon.

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 veterinary surgeon.

The veterinary medicinal product causes transient reductions in blood pressure and heart rate. In a target animal safety study conducted in eight healthy male cats, reductions in blood pressure and heart rate of up to 30% below baseline were observed for approximately four hours following administration of the recommended treatment dose of 2 mg/kg bodyweight. These effects were partially mitigated by human interaction followed by feeding of the cat, without the need for additional treatment. Therefore, the product should only be used according to a benefit-risk assessment by the responsible veterinary surgeon, in patients with congestive heart failure, cardiac arrythmias, dehydration, anaemia or other conditions that may impair tissue perfusion or oxygenation. The product must not be used in cases of severe haemodynamic instability such as hypovolaemic shock. See also section 3.3 Contraindications.

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, the product should only be used for a period of greater than 90 days following a benefit-risk assessment by the responsible veterinary surgeon.

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. Children should not have access to filled syringes. Do not leave a filled syringe unattended. 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, Inappetence
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Bradycardia, Hypotension

[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 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. However, laboratory studies in rats have shown evidence of teratogenic effects.

Pregnancy and lactation:
Do not use during pregnancy and lactation.

Fertility:
Do not use in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product causes transient decreases in blood pressure and heart rate for up to several hours after dosing. Therefore, concurrent use of other drugs that cause reductions in blood pressure and/or heart rate (e.g. sedatives, anaesthetic agents, prazosin, ACE inhibitors) should only be according to a benefit-risk evaluation by the responsible veterinary surgeon.

The veterinary medicinal product causes transient elevations in serum glucose levels and insulin resistance in cats. Therefore, concurrent use of other drugs that cause such effects (e.g. steroids) should only be according to a benefit-risk evaluation by the responsible veterinary surgeon.

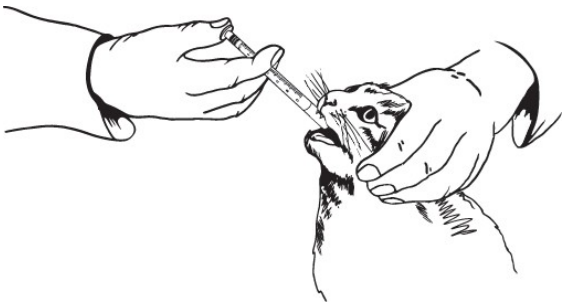
3.9 Administration routes and dosage

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.



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 diagnosed with diabetic ketoacidosis and had elevated serum liver parameters (bilirubin, ALT and AST) on day 50 of dosing. Other adverse reactions observed were consistent with those mentioned in section 3.6.

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 in the per protocol population by 6.8% compared to an untreated control group after 55 days of treatment (body weight loss of 1.7% in the control group and body weight gain of 5.1% in the capromorelin group).

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.

After oral administration, capromorelin was rapidly absorbed in cats with a T_{max} of 0.35 hours (without food). The mean half-life of capromorelin in serum following intravenous and oral administration is 0.9 and 1.1 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. Administration of capromorelin with the entire daily ration compared to fasted cats led to increases in T_{max} (1.25 versus 0.35 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.

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: 3 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.

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

Vm 52127/5043

8. DATE OF FIRST AUTHORISATION

27 June 2024

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

February 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall
Approved: 05 March 2025