ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Varenzin 23.3 mg/ml oral suspension for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

23.3 mg of molidustat equivalent to 25 mg of molidustat sodium.

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxytoluene (E321)	1.2 mg
Sorbic acid (E200)	0.8 mg
Glycerol dibehenate	
Fish oil, rich in omega-3 acids	
Sunflower oil, refined	

A white to yellow suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

For the management of non-regenerative anaemia associated with chronic kidney disease (CKD) in cats, by increasing haematocrit/packed cell volume.

3.3 Contraindications

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

Treatment with molidustat should only be initiated once the haematocrit (HCT)/packed cell volume (PCV) is <28%. Under treatment, the HCT/PCV should be monitored on a regular basis and the treatment needs to be discontinued once the upper reference range is reached to avoid the risk of thrombosis.

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 evaluated in cats less than 1 year of age or weighing less than 2 kg bodyweight. Use according to the benefit-risk assessment by the responsible veterinarian in these cases.

Hypoxia-inducible factor (HIF) -prolyl hydroxylase (PH) inhibitors have been associated with thromboembolic disease.

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

This veterinary medicinal product may cause increased erythropoietin levels, increased haemoglobin and haematocrit levels and dizziness after accidental oral ingestion. At higher dosages symptoms as increased heart rate, nausea, vomiting, headache and flushing may be possible.
Avoid accidental ingestion and contact with skin.
In order to prevent children getting access to a filled syringe, do not leave the filled syringe unattended and administer the veterinary medicinal product immediately after filling the syringe.
After administration return the unwashed syringe in the carton together with the veterinary medicinal product.
Wash hands after use.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to molidustat sodium should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats:

Common (1 to 10 animals/100 animals treated):	Vomiting
Very rare (<1 animal/10,000 animals treated, including isolated reports):	Thrombosis[1]

[1]Thrombosis might be associated to a HIF-PH inhibitors class effect.

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 pregnancy, lactation or for breeding cats. Use of the product during pregnancy and lactation, or in breeding cats is not recommended.

Laboratory studies in rats have shown at a dose of 30 mg/kg bodyweight maternotoxic effects including ocular malformations, decreased foetal weight and increased post implantation loss.

3.8 Interaction with other medicinal products and other forms of interaction

The use of the veterinary medicinal product administered concurrently with other erythropoiesis-stimulating agents, including recombinant erythropoietin drugs, has not been studied.

Phosphate binders or other products including iron supplements containing multivalent cations such as calcium, iron, magnesium, or aluminum may decrease molidustat sodium absorption.

3.9 Administration routes and dosage

For oral use.

To ensure a correct dosage, body weight should be determined as accurately as possible prior to starting treatment.

The veterinary medicinal product should be administered in accordance with the following table to ensure a dose of 5 mg molidustat sodium/kg, equivalent to 4.66 mg molidustat/kg and 0.2 ml suspension/kg once daily for up to 28 consecutive days:

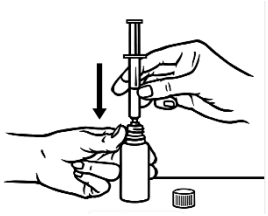
Weight Range in Kilograms (kg)	Volume (ml)
2	0.4
2.1 to 2.5	0.5
2.6 to 3.0	0.6
3.1 to 3.5	0.7
3.6 to 4.0	0.8
4.1 to 4.5	0.9
4.6 to 5.0	1.0
5.1 to 5.5	1.1
5.6 to 6.0	1.2

For treating cats with a bodyweight greater than 6.0 kg, calculate the dose using 0.2 ml/kg bodyweight and round up to the nearest 0.1 ml.

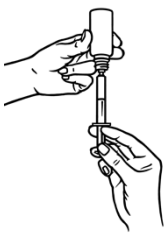
Shake the bottle well before use and remove the screw cap. Place the syringe nozzle firmly into the opening of the bottle. Turn the bottle upside down and withdraw the required volume of the veterinary medicinal product into the syringe. Turn the bottle back into an upright position before removing the syringe from the bottle. Administer the contents of the syringe into the cat's mouth. See illustrations 1 through to 4 below for administration steps:

Step 1:

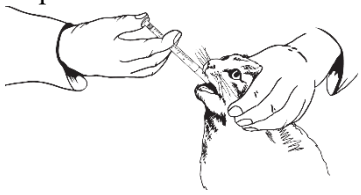
Step 2:



Step 3:



Step 4:



After administration, close bottle tightly with cap and store syringe in the carton together with the product. Do not disassemble or wash the syringe.

If the cat vomits after consuming any portion of the dose, the cat should not be re-dosed and should be considered as dosed for the day.

Monitoring and repeated treatment:
Treated cats should initially have their haematocrit (HCT) or packed cell volume (PCV) levels monitored weekly beginning about the 14th day of the 28-day treatment cycle to ensure HCT or PCV does not exceed the upper limit of the reference range. Discontinue treatment if HCT or PCV exceeds the upper limit of the reference range.

After treatment cessation the haematocrit level should be periodically checked. Prior to starting a new treatment cycle, it should be confirmed that the cat is anaemic (HCT/PCV <28%). If at the end of the current treatment cycle the cat remains anaemic, a new treatment cycle may be started without interruption in treatment.

If a cat does not respond to treatment after 3 weeks, it is recommended to re-examine the animal for any other underlying condition that may contribute to anaemia, such as iron deficiency, inflammatory diseases or blood loss. It is advised to treat the underlying condition before restarting treatment.

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

Treatment in young, healthy, non-anaemic animals resulted in elevated HCT/PCV values, and an increase in total protein, potassium and calcium. Histopathologic abnormalities in these animals included congestion of the vasculature in multiple organs.

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: QB03XA09

4.2 Pharmacodynamics

The veterinary medicinal product is a competitive and reversible inhibitor of hypoxia-inducible factor prolyl hydroxylase (HIF-PH). The inhibition of HIF-PH induces a dose-dependent increase of endogenous erythropoietin (EPO) by stabilising HIF, resulting in increased erythropoiesis (red blood cell production).

In a clinical field trial, 75 cats were evaluated for effectiveness (40 received Varenzin and 35 received a control product), 68% of cats receiving Varenzin achieved treatment success after 28 days of treatment, compared to 17% in the placebo group, with a higher number of treatment successes observed in cats with earlier stages of CKD. Treatment success was defined as an increase of ≥4% points in haematocrit observed on Study Day 28 and/or an overall 25% increase in haematocrit from baseline (Study Day 0).

4.3 Pharmacokinetics

Pharmacokinetics were investigated in healthy adult cats. After an oral dose of 5 mg molidustat sodium per kg to cats, molidustat was rapidly absorbed reaching peak plasma concentrations within an hour. Bioavailability was high (approximately 80%). With a half-life of approx. 6 hours no relevant accumulation was observed after once daily dosing. A dose proportional increase of exposure (AUC) was observed within a dose range of 2.5 to 10 mg/kg.

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: 28 days.

5.3 Special precautions for storage

Do not store above 30 ºC.

5.4 Nature and composition of immediate packaging

Amber type III glass bottle filled with 27 ml of oily suspension.

Each bottle is fitted with a polyethylene adapter and closed with a white polypropylene tamper proof child resistant screw cap.

Polypropylene oral syringe bearing a 2 ml scale with 0.1 ml graduations.

Pack size: cardboard box containing 1 bottle and 1 syringe.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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/2/25/358/001

8. DATE OF FIRST AUTHORISATION

22/01/2026

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

SPECIFIC PHARMACOVIGILANCE REQUIREMENTS:

The MAH shall record in the pharmacovigilance database all results and outcomes of the signal management process, including a conclusion on the benefit-risk balance, according to the following frequency: annually.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Varenzin 23.3 mg/ml oral suspension for cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 23.3 mg molidustat equivalent to 25 mg molidustat sodium.

3. PACKAGE SIZE

27 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 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30 °C.

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/2/25/358/001

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle (glass)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Varenzin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

23.3 mg/ml molidustat

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Varenzin 23.3 mg/ml oral suspension for cats

2. Composition

Each ml contains:

Active substance:
23.3 mg molidustat equivalent to 25 mg molidustat sodium.

Excipients:
Butylhydroxytoluene (E321) 1.2 mg
Sorbic acid (E200) 0.8 mg

A white to yellow suspension.

3. Target species

Cats 

4. Indications for use

For the management of non-regenerative anaemia associated with chronic kidney disease (CKD) in cats, by increasing haematocrit/packed cell volume.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.
Treatment with molidustat should only be initiated once the haematocrit (HCT)/packed cell volume (PCV) is <28%. Under treatment the HCT/PCV should be monitored on a regular basis and the treatment needs to be discontinued once the upper reference range is reached to avoid the risk of thrombosis.

6. Special warnings

Special precautions for safe use in the target species:
The safety of the veterinary medicinal product has not been evaluated in cats less than 1 year of age or weighing less than 2 kg bodyweight. Use according to the benefit-risk assessment by the responsible veterinarian in these cases.

Hypoxia-inducible factor (HIF) -prolyl hydroxylase (PH) inhibitors have been associated with thromboembolic disease.

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

This veterinary medicinal product may cause increased erythropoietin levels, increased haemoglobin and haematocrit levels and dizziness after accidental oral ingestion. At higher dosages symptoms as increased heart rate, nausea, vomiting, headache and flushing may be possible.
Avoid accidental ingestion and contact with skin.
In order to prevent children getting access to a filled syringe, do not leave the filled syringe unattended and administer the veterinary medicinal product immediately after filling the syringe.
After administration return the unwashed syringe in the carton together with the veterinary medicinal product.
Wash hands after use.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to molidustat sodium should avoid contact with the veterinary medicinal product.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy, lactation or for breeding cats. Use of the product during pregnancy and lactation, or breeding cats is not recommended.

Laboratory studies in rats have shown at a dose of 30 mg/kg bodyweight maternotoxic effects including ocular malformations, decreased foetal weight and increased post implantation loss.

Interaction with other medicinal products and other forms of interaction:
The use of the veterinary medicinal product administered concurrently with other erythropoiesis-stimulating agents, including recombinant erythropoietin drugs, has not been studied.

Phosphate binders or other products including iron supplements containing multivalent cations such as calcium, iron, magnesium, or aluminum may decrease molidustat sodium absorption.

Overdose:
Treatment in young healthy, non-anaemic animals resulted in elevated HCT/PCV values, and an increase in total protein, potassium and calcium. Histopathologic abnormalities in these animals included congestion of the vasculature in multiple organs.

7. Adverse events

Cats:

Common (1 to 10 animals/ 100 animals treated):	Vomiting
Very rare (<1 animal/ 10,000 animals treated, including isolated reports):	Thrombosis[1] (blood clot formation)

[1]Thrombosis might be associated to a HIF-PH inhibitors class effect.

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

For oral use.

To ensure a correct dosage, body weight should be determined as accurately as possible prior to starting treatment.

The veterinary medicinal product should be administered in accordance with the following table to ensure a dose of 5 mg molidustat sodium/kg, equivalent to 4.66mg molidustat/kg and 0.2 ml suspension/kg once daily for up to 28 consecutive days:

Weight Range in Kilograms (kg)	Volume (ml)
2	0.4
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3.1 to 3.5	0.7
3.6 to 4.0	0.8
4.1 to 4.5	0.9
4.6 to 5.0	1.0
5.1 to 5.5	1.1
5.6 to 6.0	1.2

For treating cats with a bodyweight greater than 6.0 kg, calculate the dose using 0.2 ml/kg bodyweight and round up to the nearest 0.1 ml.

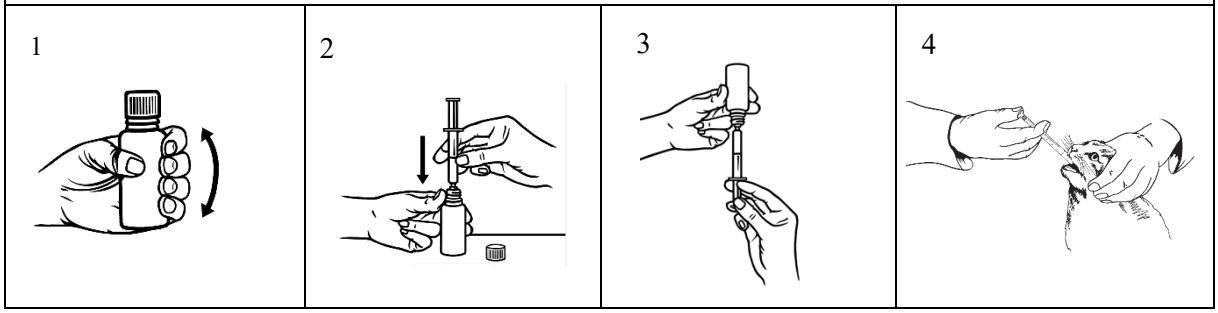
Shake the bottle well before use and remove the screw cap. Place the syringe nozzle firmly into the opening of the bottle. Turn the bottle upside down and withdraw the required volume of the veterinary medicinal product into the syringe. Turn the bottle back into an upright position before removing the syringe from the bottle. Administer the contents of the syringe into the cat's mouth.

For monolingual packaging
<A diagram showing the adminstration steps is below in Figure 1:>

For multilingual packaging
<A diagram showing administration steps is at the end of this leaflet in Figure 1.>

For monolingual packaging
<Figure 1- Administration steps>

For multilingual packaging
< Figure 1- Administration steps> </>



After administration, close bottle tightly with cap and store syringe in the carton together with the product. Do not disassemble or wash the syringe.

9. Advice on correct administration

If the cat vomits after consuming any portion of the dose, the cat should not be re-dosed and should be considered as dosed for the day.

Monitoring and Repeated Treatment:
Treated cats should initially have their haematocrit (HCT) or packed cell volume (PCV) levels monitored weekly beginning about the 14th day of the 28-day treatment cycle to ensure HCT or PCV does not exceed the upper limit of the reference range. Discontinue treatment if HCT or PCV exceeds the upper limit of the reference range.

After treatment cessation the haematocrit level should be periodically checked. Prior to starting a new treatment cycle, it is at the discretion of the veterinarian to check and confirm the cat is anaemic (HCT/PCV <28%). If at the end of the current treatment cycle the cat remains anaemic, a new treatment cycle may be started without interruption in treatment.

If a cat does not respond to treatment after 3 weeks, it is recommended to re-examine the animal for any other underlying condition that may contribute to anaemia, such as iron deficiency, inflammatory diseases or blood loss. It is advised to treat the underlying condition before restarting treatment.

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 the bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days.

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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/25/358/001

Amber type III glass bottle filled with 27 ml of oily suspension.

Each bottle is fitted with a polyethylene adapter and closed with a white polypropylene tamper proof child resistant screw cap.

Polypropylene oral syringe bearing a 2 ml scale with 0.1 ml graduations.

Pack size: cardboard box containing 1 bottle and 1 syringe.

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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