

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Varenzin 25 mg/ml oral suspension for cats

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Active substance:**

Each ml contains 25 mg molidustat sodium.

#### **Excipients:**

<b>Qualitative composition of excipients and other constituents</b>
Butylhydroxytoluene
Sorbic acid
Glycerol dibehenate
Fish oil
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 treatment of non-regenerative anaemia associated with chronic kidney disease (CKD) in cats.

#### **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 evaluated in cats less than 1 year of age or weighing less than 2 kg bodyweight.

Hypoxia-inducible factor (HIF) -prolyl hydroxylase (PH) inhibitors have been associated with thromboembolic disease. Use with caution in cats that may be predisposed to thromboembolic disease.

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

Accidental ingestion may cause flushing of the skin and/or orthostatic effects such as dizziness. In case of accidental ingestion, seek medical advice immediately 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

Target species: Cats

Common (1 to 10 animals/ 100 animals treated):	Vomiting
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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

The safety of the veterinary medicinal product has not been established during pregnancy, lactation or for breeding cats.

### 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 containing multivalent cations such as calcium, iron, magnesium or aluminium have been shown to chelate with other HIF-PH inhibitors.

Based on information in humans consider staggered administration of Varenzin and phosphate binders or iron supplements (at least 1 hour apart), to prevent potentially decreased absorption of molidustat. The veterinarian should consider monitoring iron levels.

### 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 5.0 mg/kg, equivalent to 0.2 ml/kg:

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:

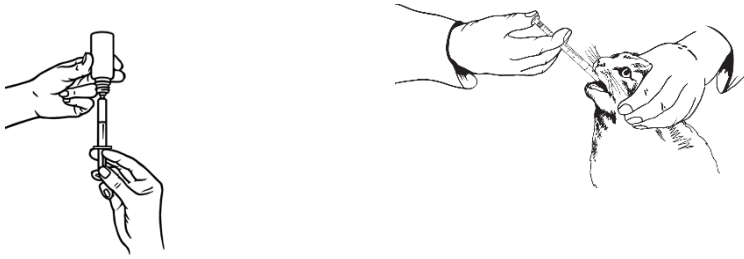


Step 2:



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.

The veterinary medicinal product should be given once daily for up to 28 consecutive days. 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. When the HCT or PCV level declines below the lower limit of the reference range, a new treatment cycle should be started.

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.

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. Treatment success was defined as an increase of  $\geq 4\%$  points in haematocrit observed on Study Day 28 and/or an overall 25% increase in haematocrit from baseline (Study Day 0).

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

None known.

**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 Pharmacotherapeutic group: other antianemic preparations.

### 4.2 Pharmacodynamics

The veterinary medicinal product is a competitive and reversible inhibitor of hypoxia-inducible factor prolyl hydroxylase (HIF-PH). Within six hours after oral administration, molidustat induced dose-dependent peak EPO concentrations in rodents, dogs, monkeys and healthy cats. The inhibition of HIF-PH induces an increase of endogenous erythropoietin (EPO) by stabilising HIF (key transcriptional activator of EPO), resulting in increased erythropoiesis (red blood cell production) in the bone marrow. This leads to a gradual increase in PCV, reticulocytes, haemoglobin and haematocrit.

### 4.3 Pharmacokinetics

#### Absorption:

After oral administration of 5 mg/kg molidustat to fasted healthy cats, plasma concentration time curves are characterised by rapid absorption with maximum plasma concentrations (C<sub>max</sub>) achieved within 1.5 hour (T<sub>max</sub>). Mean peak concentrations (C<sub>max</sub>) ranged from 3.6 to 5.1 mg/l after single dosing. Overall exposure (AUC<sub>inf</sub>) following administration of 5 mg/kg molidustat was between 8.6 and 14.1 mg/h/l, with an oral bioavailability between 63% and >84%. Oral administration to recently fed cats resulted in lower peak concentrations with comparable overall exposure.

After repeated daily administration of 2.5 and 5 mg/kg molidustat to health cats over 56 days, a slight increase of exposure (approximately 1.5-fold) was observed. In addition, exposure was considered dose proportional for AUC, with a slight trend to less than proportional rate of exposure (C<sub>max</sub>) within a dose range of 2.5 to 10 mg/kg.

#### Distribution:

An in vitro study using cat plasma showed low (18.0% to 19.8%) plasma protein binding. Plasma protein binding appeared independent of drug concentration in cats in the tested concentration range.

An in vivo study in rats assessing the organ distribution of [<sup>14</sup>C] molidustat demonstrated that the highest systemic exposure was observed in the kidneys, liver and adrenal glands. There was no relevant penetration across the blood: brain barrier. There was no detectable specific affinity to pigmented tissues. There was a limited distribution of radioactivity to blood cells. There was no evidence of irreversible binding or retention to organs and tissue.

Pharmacokinetics after intravenous administration of 5 mg/kg molidustat in cats showed a mean volume of distribution between 2.57 and 4.82 l/kg. The mean

predicted volumes of distribution in steady state ( $V_{ss}$ ) were between 0.75 and 1.01 l/kg.

### Metabolism

The primary metabolic pathways of molidustat observed in vitro were glucuronidation to form the M-1 metabolite and glycosylation to form the M-2 metabolite. The extent of metabolic turnover was determined to be 17.0% at 1 h and 47.0% following 4 h incubation. Molidustat was classified as a highly permeable compound and neither molidustat nor its metabolite M-1 were substrates or inhibitors of P-glycoprotein (P-gp). No relevant inhibitory activity was shown with metabolite M-1.

### Excretion:

Molidustat was cleared from cat plasma at a mean rate of 0.32 l/h/kg. Molidustat was mainly cleared via faeces with mean rates of 0.089 l/h/kg and 0.18 l/h/kg and to a very minor extent via urine, whereas the metabolite M-1 was mainly cleared renally with rates of 0.050 l/h/kg and 0.14 l/h/kg. After oral administration of 5 mg/kg molidustat sodium using the final formulation to fasted cats, the mean calculated half-life ranged from 4.2 h to 7.8 h.

## **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**

Keep the bottle in the outer carton.  
Do not store above 30°C.

### **5.4 Nature and composition of immediate packaging**

30 ml amber glass bottle filled with 27 ml oily suspension.

Each bottle is fitted with a PE adapter and closed with a plastic tamper proof child resistant screw cap.

Pack size: 1 bottle and 1 measuring syringe.

### **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 52127/5065

**8. DATE OF FIRST AUTHORISATION**

13 November 2025

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

November 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](http://www.gov.uk).

Approved 23 December 2025

*Gavin Hall*