

PARTICULARS TO APPEAR ON THE OUTER PACKAGE Cardboard Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Varenzin 25 mg/ml oral suspension for cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains: 25 mg molidustat sodium.

3. PACKAGE SIZE

27 ml

1 oral syringe included

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by:

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 NUMBER

Vm 52127/5065

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS Bottle- minimum particulars are required on the bottle label due to the size being under 50 ml (27 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

25 mg/ml molidustat sodium

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use by:

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Varenzin 25 mg/ml oral suspension for cats

2. Composition

Active substance:

Each ml contains: 25 mg molidustat sodium

A white to yellow suspension.

3. Target species

Cats

4. Indications for use

For the treatment of non-regenerative anaemia associated with chronic kidney disease (CKD) in cats.

5. Contraindications

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

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.

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.

Pregnancy and lactation:

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

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.

7. Adverse events

Target species: Cats

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

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

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

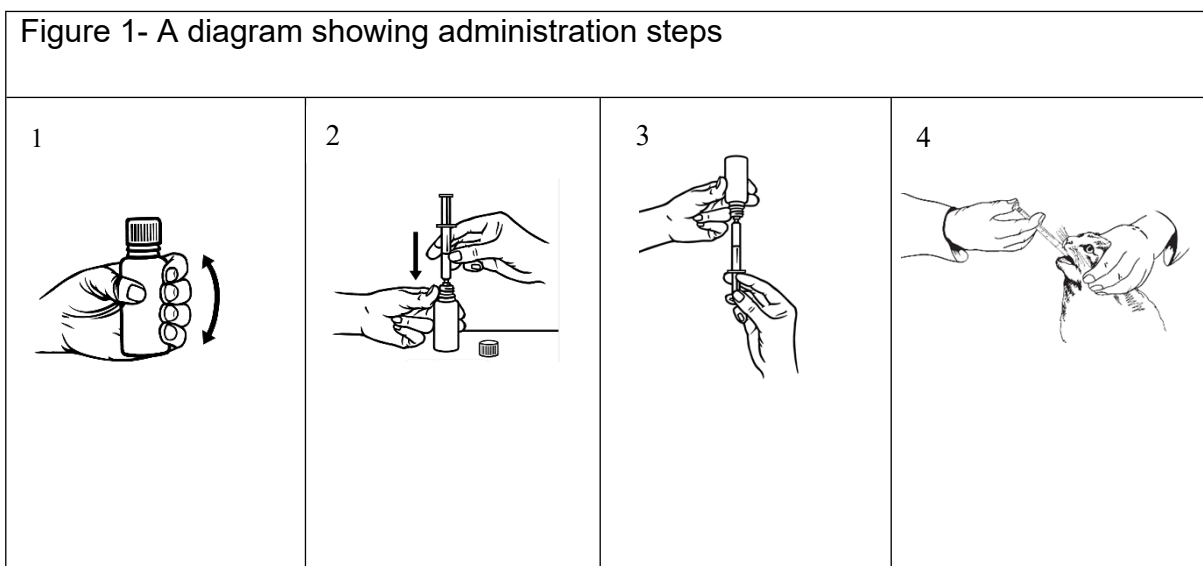
Weight Range in Kilograms (kg)	Volume (ml)
2	0.4
2.1 to 2.5	0.5
2.6 to 3.0	0.6
3.1 to 3.5	0.7
3.6 to 4.0	0.8
4.1 to 4.5	0.9

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.

A diagram showing the administration steps is below in Figure 1:



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.

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. 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).

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the bottle in the outer carton.

Do not store above 30°C

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

Shelf life after first opening the immediate packaging: 28 days

Once the bottle is opened, using the shelf-life after first opening, calculate the discard date and record in the space provided on the label.

12. Special precautions for disposal

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 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

Vm 52127/5065

Cardboard box containing 1x 30 ml amber glass bottle filled with 27 ml oily suspension and 1 measuring syringe.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH, Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany

Tel: +44 3308221732
PV.GBR@elancoah.com

Manufacturer responsible for batch release:

KVP Pharma + Veterinär Produkte GmbH, Projensdorfer Strasse 324, Kiel, 24106, Germany

17. Other information

POM-V

Approved 23 December 2025

Gavin Hall