SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lodisure 1 mg tablets for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:

Amlodipine 1.0 mg (equivalent to 1.4 mg amlodipine besilate)

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is essential for proper administration of the veterinary medicinal product
Brilliant blue FCF (E133)	1.0 mg
Yeast (dried)	
Chicken flavour	
Cellulose microcrystalline	
Sodium starch glycolate	
Magnesium stearate	

Blue, oblong tablet with light and dark spots and a scoring line on both sides.
Tablets can be divided into two equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

For the treatment of feline systemic hypertension.

3.3 Contraindications

Do not use in animals with severe hepatic disease.
Do not use in cases of hypersensitivity to the active substance or any of the excipients.
Do not use in the case of cardiogenic shock and severe aortic stenosis.

3.4 Special warnings

In cats situational hypertension (also called white coat hypertension) occurs as a consequence of the in-clinic measurement process in an otherwise normotensive animal. In case of high stress levels measurement of systolic blood pressure may lead to incorrect diagnosis of hypertension. It is recommended that stable hypertension is confirmed by multiple and repeated measurement of systolic blood pressure on different days before commencing therapy.
In case of secondary hypertension it is important to establish primary cause and/or co-morbidities of hypertension, such as hyperthyroidism, chronic kidney disease and diabetes and to treat these conditions.
Continued administration of the veterinary medicinal product over an extended period of time should be in accordance with an ongoing benefit/risk evaluation, performed by the prescribing veterinarian that includes measurement of systolic blood pressure routinely during treatment (e.g. every 2 to 3 months). If needed dosages may be adjusted.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Special caution is required in patients with hepatic disease as amlodipine is highly metabolised by the liver. Consequently amlodipine half-life may be prolonged and a lower dose may be required. As no studies have been conducted in animals with liver disease, use of the veterinary medicinal product in these animals should be based on a benefit-risk assessment by the attending veterinarian.
Older cats with severe hypertension and chronic kidney disease (CKD) may suffer from hypokalaemia as a result of their underlying disease. Administration of amlodipine may sometimes result in a decrease in serum potassium and chloride levels and could thus lead to exacerbation of hypokalaemia already present. Monitoring of those concentrations is recommended before and during treatment.
No animals with severe unstable CKD were included in the clinical trials. Use of the veterinary medicinal product in these animals should be based on a benefit-risk assessment by the attending veterinarian.
Because amlodipine may have slight negative inotropic effects, the use of the veterinary medicinal product in cardiac patients should be based on a benefit risk assessment by the veterinarian. Safety has not been tested in cats with known heart disease.
Animals weighing less than 2.5 kg were not included in the clinical trials. Animals weighing between 2 and 2.5 kg should be treated with caution and based on a benefit risk assessment by the responsible veterinarian.
Doses above 0.47 mg/kg bodyweight have not been examined in clinical trials with the veterinary medicinal product and should only be administered with caution and based on a benefit risk assessment by the attending veterinarian.

The tablets are flavoured. To avoid accidental ingestion, store tablets out of reach of animals.

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

This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to amlodipine should avoid contact with the veterinary medicinal product. Wash hands after use.
Accidental ingestion by children, may cause a decrease in blood pressure. Unused tablet parts should be placed back into the blister and carton and carefully kept away from children. In case of accidental ingestion by a child 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

Cats

Common (1 to 10 animals / 100 animals treated):	Digestive tract disorder (e.g. vomiting, diarrhoea)[a] Lethargy, Weight loss, Decreased appetite[a] Hypokalaemia
Uncommon (1 to 10 animals / 1,000 animals treated):	Hypotension

[a] Mild and transient.

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 or lactation.

Pregnancy and lactation:
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects or reproductive toxicity.
Amlodipine is excreted with the milk.
Use only in accordance with the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Concomitant use of diuretics, beta-blockers, other calcium channel blockers, inhibitors of the renin angiotensin aldosterone system, other vasodilators, alpha-2 agonists or other agents that may reduce blood pressure may cause hypotension.
Concomitant use of cyclosporin or CYP3A4 strong inhibitors (eg. ketoconazole, itraconazole) may cause increased amlodipine levels.

3.9 Administration routes and dosage

Oral use.
The tablets can be administered directly to the animal or administered with a small quantity of food.

The recommended standard starting dose is 0.125-0.25 mg amlodipine per kg bodyweight per day.

	Bodyweight range (kg)	Number of tablets a day
Standard posology:	2 to < 4	½
	≥ 4 to 8	1

To ensure a correct dosage, body weight should be determined as accurately as possible.
For cats weighing between 2 kg and 2.5 kg, please refer to section 3.5.
After two weeks of treatment, the clinical response should be re-evaluated. In case of insufficient clinical response - decrease in SBP less than 15% and SBP still > 150 mm Hg - dose may be increased by 0.5 mg (½ tablet) per day, up to a maximum dose of 0.5 mg/kg BW daily. See also section 3.5.
Response to dose adjustments should be re-evaluated after another two weeks.
In the event of clinically relevant adverse events decreasing the dose or termination of treatment should be considered.

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

Reduced appetite and weight loss occurred at a dose of 1 mg/day (corresponding to 0.32 mg/kg).
Lethargy started to occur in some cats receiving 3 mg amlodipine/daily (0.63 -1.11 mg/kg/day).
An overall shift in electrolyte balance (lowered potassium and chloride concentrations) was detected in all animals receiving 3-5 mg amlodipine/daily (0.49 - 1.56 mg/kg).
Conjunctivitis and watery discharge from the eyes was noted in the highest dosed animals, i.e. 1.02 - 1.47 mg/kg; however it is unclear if this is treatment related.
Reversable gingival hyperplasia has been described in literature after treatment with 2.5 mg of amlodipine per day for more than 300 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: QC08CA01.

4.2 Pharmacodynamics

Amlodipine is a calcium ion influx inhibitor of the dihydropyridine group (slow channel blocker or calcium ion antagonist) and inhibits the transmembrane influx of calcium ions into cardiac and vascular smooth muscle.
The mechanism of the antihypertensive action of amlodipine is due to a direct relaxant effect on vascular smooth muscle, where it acts as a peripheral arteriolar vasodilator and reduces afterload.
Amlodipine has a higher affinity for L-type calcium channels and has some affinity for T-type calcium channels. Within the kidney, L-type calcium channels are found primarily in afferent (prerenal) arterioles. Although amlodipine has a greater affinity for the vascular L-type calcium channels, it can also act on those found in the cardiac muscle and cardiac nodal tissue.
Amlodipine slightly depresses impulse formation and conduction velocity in the cardiac muscle.
In cats with systemic arterial hypertension, once daily dosing of amlodipine by oral route provides clinically significant reductions of blood pressure throughout the 24 hour interval. Due to the slow onset of action, acute hypotension is not a feature of amlodipine administration.

4.3 Pharmacokinetics

Absorption: After oral administration amlodipine is well absorbed with a mean bioavailability of approximately 80%. Following a single dose of 1 mg per cat (corresponding to 0.16 and 0.40 mg amlodipine/kg) peak blood levels of 3.0 to 35.1 ng/ml (mean Cmax 19.3 ng/ml) are measured between 2 and 6 hours (mean Tmax 4.3 h) post dose.
Distribution: Amlodipine is highly bound to plasma proteins. In vitro protein binding in cat plasma is 97%. The amlodipine volume of distribution is approximately 10 L/kg.
Biotransformation: Amlodipine is extensively metabolized in the liver to inactive metabolites.
Elimination: Amlodipine has a long plasma half-life of 33 to 86 hours (average 54 h), resulting in significant accumulation.

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 of the divided tablet: use within 24 hours.

5.3 Special precautions for storage

Do not store above 25 °C.
Divided tablets should be stored in the open blister pack.
Keep the blister package in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Blister made of PVC /aluminium / OPA with a push-through PVC-PVDC/aluminium lidding foil. Each blister contains 14 tablets.

Package sizes:
1 cardboard carton with 28 tablets
1 cardboard carton with 56 tablets
1 cardboard carton with 84 tablets
1 cardboard carton with 168 tablets
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

Dechra Regulatory B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 50406/4010

8. DATE OF FIRST AUTHORISATION

08 December 2020

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

September 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: 08 December 2025