ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lodisure 1 mg tablets for cats
Amlodipine

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Amlodipine 1.0 mg (equivalent to 1.4 mg amlodipine besilate)

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

28 tablets
56 tablets
84 tablets
168 tablets

5. TARGET SPECIES

Cats

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life of divided tablets after first opening the immediate packaging: 1 day.

11. SPECIAL STORAGE CONDITIONS

Divided tablets should be stored in the open blister pack.
Keep the blister package in the outer carton in order to protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription
POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 50406/4010

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

ALUMINIUM BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lodisure 1 mg tablets
Amlodipine

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Lodisure 1 mg tablets for cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:
Lelypharma BV
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lodisure 1 mg tablets for cats
Amlodipine

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each tablet contains:

Active substance:
Amlodipine 1.0 mg (equivalent to 1.4 mg amlodipine besilate)

Excipients:
Brilliant blue FCF (E133) 1.0 mg

Blue, oblong tablet scored on both sides.
The tablets can be divided into two equal parts.

4. INDICATION(S)

For the treatment of feline systemic hypertension.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

The following adverse events were commonly reported in clinical trials: mild and transient digestive tract disorders (e.g. vomiting, decreased appetite, diarrhoea), lethargy, weight loss and reduced serum levels of potassium. Hypotension was uncommonly observed during clinical trials.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cats 

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.

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

For cats weighing between 2 kg and 2.5 kg, please refer to section 12.
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 12.
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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

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11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special temperature storage conditions.
Divided tablets should be stored in the open blister pack.
Keep the blister package in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton after {EXP}. The expiry date refers to the last day of that month.
Shelf life of divided tablets after first opening the immediate packaging: 1 day.

12. SPECIAL WARNING(S)

Special warnings for each target species:
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 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.

Special precautions for use in animals:
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 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 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 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 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 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.

Pregnancy and lactation:
There has been no evidence of teratogenicity or reproductive toxicity in studies with rats and rabbits. Amlodipine is excreted with the milk.
The safety of amlodipine has not been established during pregnancy or lactation in cats.
Use only in accordance with the benefit/risk assessment by the responsible veterinarian.

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 (e.g. ketoconazole, itraconazole) may cause increased amlodipine levels.

Overdose (symptoms, emergency procedures, 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..

Incompatibilities:
Not applicable

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

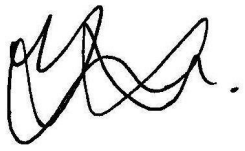
14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Cardboard box of 28, 56, 84 or 168 tablets.
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

POM-V	Prescription Only Medicine



Approved: 08 December 2020