

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard box containing 3 blisters of 30 tablets

Cardboard box containing 10 blisters of 100 tablets

Cardboard box containing 20 blisters of 200 tablets

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

Amodip 1.25 mg Chewable Tablets

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each tablet contains:

Amlodipine 1.25 mg (Equivalent to 1.73 mg of amlodipine besilate)

**3. PACKAGE SIZE**

30 tablets

100 tablets

200 tablets

**4. TARGET SPECIES**

Cats

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Oral use.

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once divided use within 24 hours.

Shelf life of halved tablets: 24 hours

## **9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 30°C.

Any unused half tablets should be returned to the blister pack.

## **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**

Ceva Sante Animale  
8 rue de Logrono  
33500 Libourne  
France

## **14. MARKETING AUTHORISATION NUMBERS**

Vm 14966/5022  
Vm 14966/3021

## **15. BATCH NUMBER**

Lot

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**  
**BLISTER**

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

Amodip 

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

1.25mg of amlodipine

**3. BATCH NUMBER**

Lot

**4. EXPIRY DATE**

Exp. {mm/yyyy}

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

Amodip 1.25 mg Chewable Tablets for Cats

**2. Composition**

Each tablet contains:

**Active substance**

Amlodipine 1.25 mg  
(Equivalent to 1.73 mg of amlodipine besilate)

Oblong in shape, score line on one side, beige to light brown tablets.  
Tablets can be divided into two equal parts.

**3. Target species**

Cats

**4. Indications for use**

Amodip is intended for the treatment of systemic hypertension in cats.

**5. Contraindications**

Do not use in the case of cardiogenic shock and severe aortic stenosis.

Do not use in cases of severe hepatic failure.

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

**6. Special warnings**

The primary cause and/or co-morbidities of hypertension, such as hyperthyroidism, chronic kidney disease and diabetes, should be identified and treated.

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 repeated measurement of systolic blood pressure on different days before commencing therapy.

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 6 to 8 weeks).

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. 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.

Administration of amlodipine may sometimes result in a decrease in serum potassium and chloride levels. Monitoring of those levels is recommended during treatment. Older cats with hypertension and chronic kidney disease (CKD) may also suffer from hypokalaemia as a result of their underlying disease.

The safety of amlodipine has not been established in cats weighing less than 2.5 kg. Safety has not been tested in cats with cardiac failure. Use in these cases should be based on a benefit risk assessment by the veterinarian.

The chewable tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

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

This product may decrease blood pressure. In order to reduce the risk of accidental ingestion by children, do not take the tablets out of blisters until ready to administer to the animal. Return part-used tablets into the blister and carton. 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 amlodipine should avoid contact with the veterinary medicinal product. Wash hands after use.

Pregnancy and lactation:

Laboratory studies in rodents have not produced any evidence of teratogenicity or reproductive toxicity. The safety of amlodipine has not been established during pregnancy and lactation in cats. Use only in accordance with the risk-benefit assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Concomitant use of amlodipine with other agents that may reduce blood pressure may cause hypotension. These agents include: diuretics, beta-blockers, other calcium channel blockers, inhibitors of the renin angiotensin aldosterone system (renin inhibitors, angiotensin II receptor blockers, angiotensin converting enzyme inhibitors (ACEI), and aldosterone antagonists), other vasodilators and alpha-2 agonists. It is advised to measure blood pressure before administering amlodipine with these agents and to ensure cats are adequately hydrated.

However, in clinical cases of feline hypertension, no evidence of hypotension occurring as a result of combining amlodipine with the ACEI benazepril was observed.

Concomitant use of amlodipine with negative chronotropes and inotropes (such as beta-blockers, cardioselective calcium channel blockers and antifungal azoles (eg. itraconazole)) may reduce force and rate of contraction of the heart muscle. Particular

attention must be paid before administering amlodipine with these drugs in cats with ventricular dysfunction.

The safety of concomitant use of amlodipine and the anti-emetic agents dolasetron and ondansetron has not been evaluated in cats.

Overdose:

Reversible hypotension may occur in cases of accidental overdose. Therapy is symptomatic.

After administration of 0.75 mg/kg and 1.25 mg/kg once daily for 6 months to healthy young adult cats, hyperplastic gingivitis, reactive lymphoid hyperplasia in mandibular lymph nodes, and increased Leydig cell vacuolisation and hyperplasia were seen. At the same dose levels plasma potassium and chloride levels were decreased and an increase in urinary volume associated with decreased urinary specific gravity was observed. These effects are unlikely to be observed under clinical conditions with short term accidental overdosing.

In a small two-week tolerance study of healthy cats (n=4), doses between 1.75 mg/kg and 2.5 mg/kg were administered, and mortality (n=1) and severe morbidity (n=1) occurred.

Major incompatibilities:

Not Applicable

**7. Adverse events**

Cats:

Very common (>1 animal / 10 animals treated):	Emesis <sup>1</sup> , Gingival hyperplasia <sup>2</sup> Enlarged lymph node (localised) <sup>2,3</sup>
Common (1 to 10 animals / 100 animals treated):	Diarrhoea <sup>1</sup> Lethargy, Dehydration, Anorexia <sup>1</sup>

<sup>1</sup>Mild and transient

<sup>2</sup>At the dose of 0.25 mg/kg, observed in healthy young adult cats but not in the clinical trial with older hypertensive cats. This does not usually require stopping the treatment.

<sup>3</sup>Submandibular

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](mailto:adverse.events@vmd.gov.uk)

## 8. Dosage for each species, routes and method of administration

Oral use

Amlodipine tablets should be administered orally at a recommended starting dose of 0.125 -0.25 mg/kg/day.

After 14 days of treatment, the dose may subsequently be doubled or increased up to 0.5 mg/kg once daily if adequate clinical response has not been achieved (e.g. systolic blood pressure remaining over 150 mmHg or a decrease of less than 15 % from the pre-treatment measurement).

Weight of cat (kg)	Starting dose (number of tablets)
2.5 - 5.0	0.5
5.1 - 10.0	1
10.1 and above	2

## 9. Advice on correct administration

Tablets can be broken in halves to adapt the dosage to the weight of the cat most accurately.

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

## 10. Withdrawal periods

Not applicable.

## 11. Special storage precautions

Keep out of the sight and reach of children.

Any unused half tablets should be returned to the blister pack.

Do not store above 30°C.

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

Shelf life of halved tablets: 24 hours

Any half tablets remaining after 24 hours should be discarded.

## 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 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 14966/5022

Vm 14966/3021

Cardboard box of 30 tablets  
Cardboard box of 100 tablets  
Cardboard box of 200 tablets

Not all pack sizes may be marketed.

### **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](http://www.gov.uk).

### **16. Contact details**

Marketing authorisation holder:

Ceva Sante Animale  
8 rue de Logrono  
33500 Libourne  
France

Contact details to report suspected adverse reactions:

Ceva Animal Health Ltd  
Explorer House  
Mercury Park  
Wycombe Lane  
Wooburn Green  
High Wycombe  
Buckinghamshire  
HP10 0HH  
United Kingdom

Manufacturer responsible for batch release:

Ceva Santé Animale  
Boulevard de la communication  
Zone Autoroutière  
53950 LOUVERNE  
FRANCE

**17. Other information**

POM-V

Veterinary Medicinal product subject to prescription  
For animal treatment only

*Gavin Hall*  
Approved: 26 September 2025