PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of 3 blisters of 30 tablets
Cardboard box of 10 blisters of 100 tablets
Cardboard box of 20 blisters of 200 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amodip 1.25 mg chewable tablets for cats

amlodipine (as besilate)

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains Amlodipine1.25 mg (Equivalent to 1.73 mg of amlodipine besilate)

3. PHARMACEUTICAL FORM

Chewable tablet

4. PACKAGE SIZE

30 tablets
100 tablets
200 tablets

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life of halved tablets: 24 hours
Any half tablets remaining after 24 hours should be discarded.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.
Any unused half tablets should be returned to the blister pack.

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.

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

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

16. MARKETING AUTHORISATION NUMBER

Vm 15052/4141

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister of 10 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amodip 1.25 mg chewable tablets 

amlodipine (as besilate)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET:

Amodip 1.25 mg chewable 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
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 Louverné
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Amodip 1.25 mg chewable tablets for cats

amlodipine (as besilate)

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

Each tablet contains
Active substance:

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

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

4. INDICATION(S)

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 known hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Mild and transient emesis was a very common adverse event in the clinical trial (13%). Common adverse events were mild and transient digestive tract disorders (e.g. anorexia or diarrhoea), lethargy and dehydration.
At the dose of 0.25 mg/kg, mild hyperplastic gingivitis with some enlargement of submandibular lymph nodes has been observed very commonly in healthy young adult cats in clinical trials and very rarely in elderly cats based on the post-marketing experience. This does not usually require stopping the treatment.

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.
Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

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

Keep out of the sight and reach of children.
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. 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 WARNING(S)

Special warnings for each target species:
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 use in animals:
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 (symptoms, emergency procedures, antidotes):
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.

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

Medicines should not be disposed of via wastewater or household waste.
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

September 2022

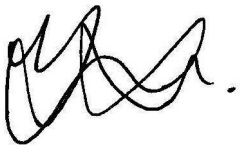
15. OTHER INFORMATION

In a clinical study, a field-representative sample of client-owned cats with persistent hypertension (systolic blood pressure (SBP) >165 mmHg) were randomised to receive amlodipine (initial dose of 0.125-0.25 mg/kg, rising to 0.25 - 0.50 mg/kg if response was not satisfactory after 14 days) or placebo, once daily. SBP was measured after 28 days and treatment was considered successful if SBP was reduced by 15% or more of pre-treatment SBP or to below 150 mmHg. 25 out of 40 cats (62.5%) given amlodipine were successfully treated compared with 6 out of 34 (17.6%) given placebo. It was estimated that amlodipine treated animals have 8 times greater odds of treatment success than placebo treated cats (OR 7.94, 95% confidence interval 2.62 - 24.09).

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



Approved: 13 September 2022