SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Telmitraxx 4 mg/ml oral solution for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Telmisartan	4 mg

Excipients:

Benzalkonium chloride	0.1 mg
Disodium edetate	1.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution
Clear and colourless to yellow solution practically free from particles.

4. CLINICAL PARTICULARS

4.1 Target species

Cats

4.2 Indications for use, specifying the target species

Reduction of proteinuria associated with chronic kidney disease (CKD).

4.3 Contraindications

Do not use during pregnancy or lactation (see also section 4.7).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i). Special precautions for use in animals

The safety and efficacy of telmisartan has not been tested in cats under the age of 6 months.

It is good clinical practice to monitor the blood pressure of cats receiving telmisartan which are under anaesthesia.
Due to the mode of action of the veterinary medicinal product, transient hypotension may occur. Symptomatic treatment, e.g. fluid therapy, should be provided in case of any clinical signs of hypotension.
As known from substances acting on the Renin-Angiotensin-Aldosterone System (RAAS), a slight decrease in red blood cell count may occur. Red blood cell count should be monitored during therapy. Substances acting on the RAAS may lead to a reduction in glomerular filtration rate and worsening renal function in cats with severe kidney disease. The safety and efficacy of telmisartan in such patients has not been investigated. When using this veterinary medicinal product in cats with severe kidney disease, it is advisable to monitor renal function (plasma creatinine concentration).

ii). Special precautions to be take by the person administering the veterinary medicinal product to animals

This product may cause adverse effects, such as headache, dizziness or hypotension. Avoid oral ingestion by children. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
This product may cause eye-irritation. Avoid eye contact. In case of accidental eye contact, rinse eyes with water.
Pregnant women should take special care to avoid contact with the veterinary medicinal product because substances acting on the RAAS, such as Angiotensin Receptor Blockers (ARBs) and ACE inhibitors (ACEis), have been found to affect the unborn child during pregnancy in humans.
Telmisartan may cause allergic reactions. People with hypersensitivity to telmisartan or other sartans/ARBs should avoid contact with the veterinary medicinal product.
Wash hands after use.

iii). Other precautions

Not applicable

4.6 Adverse reactions (frequency and seriousness)

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Gastrointestinal signs (regurgitation[1], vomiting, diarrhoea)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Elevated liver enzymes[2] Decreased red blood cell counts (see section 3.5).

[1] Mild and intermittent
[2] Values normalised within a few days following cessation of therapy.

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.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established in breeding, pregnant or lactating cats.
Do not use during pregnancy and lactation (see section 4.3).

4.8 Interaction with other medicinal products and other forms of interaction

During concomitant therapy with amlodipine at the recommended dose, no clinical evidence of hypotension was observed.
No drug-drug interactions are known from available data in cats with CKD for the use of telmisartan and other medicinal products that interfere with RAAS (such as ARBs or ACEis). The combination of agents targeting the RAAS may alter renal function.

4.9 Amount(s) to be administered and administration route

Oral use.

The recommended dose is 1 mg telmisartan/kg body weight (0.25 ml/kg body weight).
The veterinary medicinal product is to be administered once daily directly into the mouth or with a small amount of food.
The veterinary medicinal product is an oral solution and is well accepted by most cats.
The solution should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a ml scale.
After administration of the veterinary medicinal product, close the bottle tightly with the cap, wash the measuring syringe with water and let it dry.
To avoid contamination, use the provided syringe only to administer the veterinary medicinal product.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

After administration of telmisartan up to 5 times the recommended dose for 6 months to young adult healthy cats, adverse reactions observed were consistent with those mentioned in section 4.6.
Administration of telmisartan at overdose (3 to 5 times of the recommended dose for 6 months) resulted in marked reductions in blood pressure, decreases in red blood cell count (effects attributable to the pharmacological activity of the product) and increases in Blood Urea Nitrogen (BUN).

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Agents acting on the renin-angiotensin system, angiotensin II antagonists, plain.

ATC Vet Code: QC09CA07

5.1 Pharmacodynamic properties

Telmisartan is an orally active and specific angiotensin II receptor (subtype AT1) antagonist which causes a dose-dependent decrease in mean arterial blood pressure in mammalian species, including the cat. In a clinical trial in cats with chronic kidney disease, a reduction in proteinuria was seen within the first 7 days after the start of treatment.

Telmisartan displaces angiotensin II from its binding site at the AT1 receptor subtype. Telmisartan selectively binds to the AT1 receptor and does not show affinity for other receptors, including AT2 or other less characterised AT receptors. Stimulation of the AT1 receptor is responsible for pathologic effects of angiotensin II in the kidney and other organs associated with angiotensin II such as vasoconstriction, retention of sodium and water, increased aldosterone synthesis and organ remodelling. Effects associated with stimulation of the AT2 receptor such as vasodilatation, natriuresis and inhibition of inappropriate cell growth are not suppressed. The receptor binding is long lasting due to the slow dissociation of telmisartan from the AT1 receptor binding site. Telmisartan does not exhibit any partial agonist activity at the AT1 receptor.

Hypokalaemia is associated with CKD, however telmisartan does not affect potassium excretion, as shown in the clinical field trial in cats.

5.2 Pharmacokinetic particulars

Absorption
Following oral administration of 1 mg/kg body weight telmisartan to cats, plasma-concentration-time curves of the parent compound are characterised by rapid absorption, with maximum plasma concentrations (Cmax) achieved after 0.5 hours (tmax). For both, Cmax-values, and AUC-values, a dose proportional increase over the dose range from 0.5 mg/kg to 3 mg/kg was observed. As determined by AUC, food consumption does not affect the overall extent of absorption of telmisartan.

Telmisartan is highly lipophilic and has rapid membrane permeability kinetics, which facilitates easy distribution into tissue. No significant gender effect was seen.

No clinically relevant accumulation was observed following multiple dose administration once daily for 21 days. The absolute bioavailability after oral administration was found to be 33%.

Distribution
In vitro studies in human, dog, mouse and rat plasma showed a high plasma protein binding (>99.5%), mainly to albumin and α-1-acid glycoprotein.

Metabolism
Telmisartan is metabolised by conjugation to the glucuronide of the parent compound. No pharmacological activity has been shown for the conjugate. From in vitro and ex vivo studies with feline liver microsomes it can be concluded that telmisartan is effectively glucuronidated in the cat. The glucuronidation resulted in the formation of the 1-O-acylglucuronide metabolite of telmisartan.

Elimination
The terminal elimination half-life (t1/2) ranged from 7.3 hours to 8.6 hours, with mean value 7.7 hours. After oral administration, telmisartan is almost exclusively excreted in the faeces mainly as the unchanged active substance.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Disodium edetate
Hydroxyethylcellulose
Sodium hydroxide (for pH adjustment)
Hydrochloric acid, diluted (for pH adjustment)
Maltitol
Water, purified

6.2 Major Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 21 months
Shelf life after first opening the immediate packaging: 6 months

6.4 Special precautions for storage

Store below 30°C
Store in the original container in order to protect from light.

6.5 Nature and composition of immediate packaging

One HDPE bottle filled with 30, 60, 90 or 200 ml.
Each bottle is closed with an LDPE plug-in adapter and a tamper-proof polypropylene (PP) closure.
Pack size of one bottle and one measuring syringe (3 ml, LDPE barrel and piston, PS plunger).
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 36408/5016

9. DATE OF FIRST AUTHORISATION

21 July 2023

10. DATE OF REVISION OF THE TEXT

July 2023

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Approved 21 July 2023