[Version 9,01/2022]

ANNEX I

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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzalkonium chloride solution	0.1 mg
Maltitol	
Hydroxyethylcellulose	
Disodium edetate	1.0 mg
Water, purified	
Sodium hydroxide	
Hydrochloric acid, dilute	

Clear and colourless to yellow solution practically free from particles

3. CLINICAL INFORMATION

3.1 Target species

Cats

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use during pregnancy or lactation (see also section 3.7).
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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).

Special precautions to be taken 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

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.

3.7 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.

3.8 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 in cats with CKD may alter renal function.

3.9 Administration routes and dosage

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.

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

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 3.6.
Administration of telmisartan at overdose (3 to 5 times 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 veterinary medicinal product) and increases in Blood Urea Nitrogen (BUN).
In the event that hypotension does occur, symptomatic treatment, e.g. fluid therapy, should be provided.

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

[For MRP/DCP/SRP and national procedures: To be completed in accordance with national requirements after conclusion of the MRP/DCP/SRP.]

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QC09CA07

4.2 Pharmacodynamics

Telmisartan is an orally active and specific angiotensin II receptor (subtype AT_1) 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 AT_1 receptor subtype. Telmisartan selectively binds to the AT_1 receptor and does not show affinity for other receptors, including AT_2 or other less characterised AT receptors. Stimulation of the AT_1 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 AT_2 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 AT_1 receptor binding site. Telmisartan does not exhibit any partial agonist activity at the AT_1 receptor.
Hypokalaemia is associated with CKD, however telmisartan does not affect potassium excretion, as shown in the clinical field trial in cats.

4.3 Pharmacokinetics

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 (C_{max}) achieved after 0.5 hours (t_{max}). For both, C_{max}-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 ($t_{1/2}$) 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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

5.3 Special precautions for storage

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

5.4 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.

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

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

Alfasan Nederland B.V.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

<Date of first authorisation:> <{DD/MM/YYYY}> <{DD month YYYY}.>

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

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database. (*https://medicines.health.europa.eu/veterinary*)

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Telmitraxx 4 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Telmisartan 4 mg/ml

3. PACKAGE SIZE

30 ml
60 ml
90 ml
200 ml

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp

Once opened, use within 6 months. Use by __/__

9. SPECIAL STORAGE PRECAUTIONS

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

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

Alfasan Nederland B.V.

14. MARKETING AUTHORISATION NUMBERS

EU/0/00/000/000

15. BATCH NUMBER

Lot

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

HDPE bottles of 30 ml, 60 ml, 90 ml or 200 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Telmitraxx 4 mg/ml oral solution

2. STATEMENT OF ACTIVE SUBSTANCES

Telmisartan 4 mg/ml

3. TARGET SPECIES

Cats

4. ROUTES OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 6 months.

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Telmitraxx 4 mg/ml oral solution for cats

2. Composition

Each ml contains:

Active substance:
Telmisartan 4 mg

Excipients:
Benzalkonium chloride solution 0.1 mg
Disodium edetate 1.0 mg

Clear and colourless to yellow solution practically free from particles

3. Target species

Cats

4. Indications for use

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

5. Contraindications

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

6. Special warnings

Special warnings:
None.

Special precautions for safe use in the target species:
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).

Special precautions to be taken 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.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in breeding, pregnant or lactating cats.
Do not use during pregnancy and lactation.

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 in cats with CKD may alter renal function.

Overdose:
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 7.
Administration of telmisartan at overdose (3 to 5 times 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 veterinary medicinal product) and increases in Blood Urea Nitrogen (BUN).
In the event that hypotension does occur, symptomatic treatment, e.g. fluid therapy, should be provided.

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

7. Adverse events

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 6).

[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 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 using the contact details at the end of this leaflet, or via your national reporting system (national system details).

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

Oral use.

The recommended dose is 1 mg telmisartan/kg body weight (0.25 ml/kg body weight).

9. Advise on correct administration

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.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30°C.
Store in the original container in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and bottle after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the container: 6 months

12. Special precautions for disposal

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

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> <or> <pharmacist> 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

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.

15. Date on which the package leaflet was last revised

DD month YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database. (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

Marketing authorisation holder
Alfasan Nederland BV
Kuipersweg 9
3449 JA Woerden
The Netherlands.

Manufacturer responsible for batch release:
LelyPharma B.V.
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

Alfasan Nederland BV
Kuipersweg 9
3449 JA Woerden
The Netherlands.

Local representatives and contact details to report suspected adverse reactions:

[For MRP/DCP/SRP and national procedures: To be completed nationally.]