PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Telmitraxx 4 mg/ml oral solution for cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES
Telmisartan	4 mg/ml
Benzalkonium chloride	0.1 mg
Disodium edetate	1.0 mg

3. PACKAGE SIZE
30 ml
60 ml
90 ml
200 ml

4. TARGET SPECIES
Cats

5. INDICATION(S)

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/5016

15. BATCH NUMBER

Lot

16. SPECIAL WARNING(S), IF NECESSARY

Telmisartan may occasionally cause severe allergic reactions.
Pregnant women and women of childbearing age should exercise caution when handling this product.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V To be supplied only on veterinary prescription

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
HDPE BOTTLES OF 30 ML, 60 ML, 100 ML OR 200 ML

1. NAME OF THE VETERINARY MEDICINAL PRODUCT
Telmitraxx 4 mg/ml oral solution for cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES
Telmisartan	4 mg/ml
Benzalkonium chloride	0.1 mg
Disodium edetate	1.0 mg

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

9. BATCH NUMBER
Lot {number}

10. PACKAGE SIZE
30 ml
60 ml
90 ml
200 ml

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY
Telmisartan may occasionally cause severe allergic reactions.
Pregnant women and women of childbearing age should exercise caution when handling this product.

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

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

For animal treatment only.

POM-V To be supplied only on veterinary prescription

15. MARKETING AUTHORISATION NUMBER

Vm 36408/5016

PARTICULARS TO APPEAR ON THE 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 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 WARNING(S)
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 (see the section on contradictions).

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	Elevated liver enzymes[2] Decreased red blood cell counts (see section 3.5).

(<1 animal / 10,000 animals treated, including isolated reports):	

[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. 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><the local representative of 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, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.

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

9. ADVICE 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 PERIOD(S)

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

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
Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.>

16. CONTACT DETAILS

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>:>

Approved 21 July 2023