SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 10 mg/ml oral solution for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Telmisartan 10 mg

Excipients:
Benzalkonium chloride 0.1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral solution.
Clear, colourless to yellowish viscous solution.

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) in cats.
Treatment of systemic hypertension in cats

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

The safety and efficacy of telmisartan for the management of systemic hypertension above 200 mmHg has not been investigated.

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 the veterinary medicinal product 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. The dosage of telmisartan should be reduced if systolic blood pressure (SBP) is consistently lower than 120 mmHg or if there are concurrent 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 product in cats with severe kidney disease, it is advisable to monitor renal function (plasma creatinine concentration).

In cats with hypertension it is good clinical practice to regularly monitor blood pressure.

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

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid eye contact. In case of accidental eye contact, rinse eyes with water.
Wash hands after use.
Pregnant women should take special care to avoid contact with the 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.

People with hypersensitivity to telmisartan or other sartans/ARBs should avoid contact with the veterinary medicinal product.

iii) Special precautions for the protection of the environment

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Gastrointestinal signs (regurgitation[1], vomiting[2] diarrhoea[2)]. Elevated renal parameters (creatinine and/or blood urea nitrogen), chronic renal failure.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Elevated liver enzymes[3] Decreased red blood cell counts (see section 4.5).

[1] Mild and intermittent
[2] Vomiting and diarrhoea are commonly reported when given at the initial treatment dose of 2 mg/kg for systemic hypertension. Mild and transient
[3] 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 also the last section of 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

No drug-drug interactions are known from available data in cats with CKD and/or hypertension for the use of telmisartan and other medicinal products that lower blood pressure (such as amlodipine) or interfere with RAAS (such as ARBs or ACEis). The combination of such agents may lead to additive hypotensive effects or may alter renal function.

During concomitant therapy with amlodipine at the recommended dose for the reduction of proteinuria associated with chronic kidney disease (CKD) in cats, no clinical evidence of hypotension was observed.

4.9 Amount(s) to be administered and administration route

Oral use.

The 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.

CKD – amounts to be administered once daily:
The recommended dose is 1 mg telmisartan/kg body weight.

Dosing: 1 mg telmisartan/kg body weight	
Strength [mg/ml]	Dosage/kg bodyweight [ml]
10	0.1

Systemic hypertension – amounts to be administered once daily:
The initial recommended dose is 2 mg telmisartan/kg body weight.

Dosing: 2 mg telmisartan/kg body weight	
Strength [mg/ml]	Dosage/kg bodyweight [ml]
10	0.2

After 4 weeks, the dosage of telmisartan may be reduced in cats with systolic blood pressure (SBP) of less than 140 mmHg (in 0.5 mg/kg increments) at the discretion of the veterinarian.
If the SBP increases over the course of the disease the daily dose may be increased again up to 2 mg/kg.
The target SBP range is between 120 and 140 mmHg. If SBP is below the target or if there are concurrent signs of hypotension, please refer to section 4.5.

Systemic hypertension associated with CKD – amounts to be administered once daily:

The dosing regimen for hypertensive cats with concomitant chronic kidney disease is as described above for systemic hypertension except that for these cats the recommended minimum effective dose is 1 mg/kg.

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

After administration of up to 5 mg/kg body weight for 6 months to young adult healthy cats, adverse reactions observed were consistent with those mentioned in section 4.6.

Administration of the product at overdose (up to 5 mg/kg body weight 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).

In the event that hypotension does occur, symptomatic treatment, e.g. fluid therapy, should be provided.

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 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 with 1 mg/kg. In a further clinical trial in cats with hypertension a reduction in mean systolic blood pressure was achieved with a dose of 2 mg/kg. Due to the combination of these pharmacodynamic properties, telmisartan is an appropriate treatment for cats with concomitant hypertension and CKD.

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.

5.2 Pharmacokinetic particulars

Absorption
Following oral administration of 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium chloride
Hydroxyethylcellulose
Sodium hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Maltitol
Purified water

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:
18 months.
Shelf life after first opening the immediate packaging: 6 months.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

One HDPE bottle filled with:
35 ml
Each bottle is closed with an LDPE plug-in adapter and a tamper-proof child resistant closure.
Pack size of one bottle and one measuring syringe in a cardboard box.

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

Medicines should not be disposed of via wastewater.
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

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 61700/5080

9. DATE OF FIRST AUTHORISATION

18 May 2018

10. DATE OF REVISION OF THE TEXT

September 2025

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.
POM-V

Gavin Hall
Approved: 17 September 2025