ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 4 mg/ml oral solution for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One ml contains

Active substance
Telmisartan 4 mg

Excipient:
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.

4.3 Contraindications

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

4.4 Special warnings

None.

4.5 Special precautions for use

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 Semintra 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.

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 accidential 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 (ACEi), 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.

4.6 Adverse reactions (frequency and seriousness)

The following mild and transient gastrointestinal signs have rarely been observed in a clinical study (in order of decreasing frequency): mild and intermittent regurgitation, vomiting, diarrhoea or soft faeces.

Elevated liver enzymes have been very rarely observed and values normalised within a few days following cessation of therapy.

Effects attributable to the pharmacological activity of the product observed at the recommended treatment dose included reductions in blood pressure and decreases in red blood cell counts.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

The safety of Semintra has not been established in breeding, pregnant or lactating cats.
Do not use during pregancy or laction (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.

4.9 Amounts 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 product is to be administered once daily directly into the mouth or with a small amount of food.
Semintra 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 kg-body weight scale.

After administration close bottle tightly with cap.

To avoid contamination, use the provided syringe only to administer Semintra.

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

After administration of up to 5-fold of the recommended dose for 6 months, no adverse reactions were observed other than those mentioned in section 4.6.

Administration of the product at overdose (up to 5-fold 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). These effects are unlikely to be observed under clinical conditions.
However, in the event that transient hypotension does occur, symptomatic treatment, e.g. fluid therapy, should be provided.

4.11 Withdrawal period

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: angiotensin II antagonists, plain, telmisartan
ATCvet code: QC09CA07

5.1 Pharmacodynamic properties

Telmisartan is an orally active and specific angiotensin II receptor (type 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 remodeling. 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 type AT_1 receptor.

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

5.2 Pharmacokinetic properties

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 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 with faeces mainly as unchanged compound.

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 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: 3 years
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

Cardboard box containing one 45 ml HDPE bottle filled with 30 ml closed with a LDPE plug-in adapter and a tamper-proof child resistant closure and a measuring syringe.

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

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}

10. DATE OF REVISION OF THE TEXT

{MM/YYYY}

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER ING RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY OR USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
(Carton box)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 4 mg/ml oral solution for cats
Telmisartan

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Telmisartan 4 mg/ml

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

30 ml
(1 measuring syringe)

5. TARGET SPECIES

Cats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life of opened bottle: 6 months.

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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

Read the package leaflet before use.

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

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

16. MARKETING AUTHORISATION NUMBER(S)

EU/0/00/000/000

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (bottle)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 4 mg/ml oral solution for cats
Telmisartan

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Telmisartan 4 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

30 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD

Withdrawal period: Not applicable.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use by ....

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Semintra 4 mg/ml oral solution 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 and manufacturer
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 4 mg/ml oral solution for cats
Telmisartan

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

One ml contains:

Telmisartan	4 mg
Benzalkonium chloride	0.1 mg

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use during pregnancy or lactation. See section “Use during pregnancy or lactation”.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

The following mild and transient gastrointestinal signs have rarely been observed in a clinical study (in order of decreasing frequency): mild and intermittent regurgitation, vomiting, diarrhoea or soft faeces may occur.

Elevated liver enzymes have been very rarely observed and values normalized within a few days following cessation of therapy.

Effects attributable to the pharmacological activity of the product observed at the recommended treatment dose included reductions in blood pressure and decreases in red blood cell counts.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)

- very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

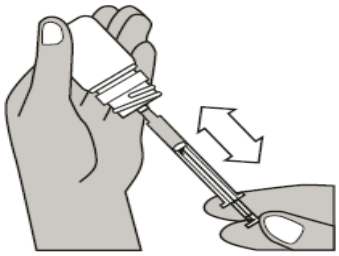
Cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

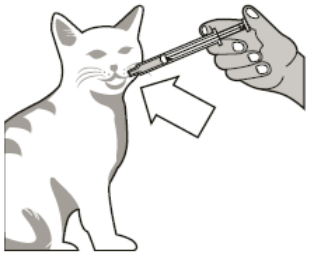
Oral use.

The recommended dose is 1 mg telmisartan/kg body weight (0.25 ml/kg body weight).
The product is to be administered once daily directly into the mouth or with a small amount of food.
Semintra is an oral solution and is well accepted by most cats.

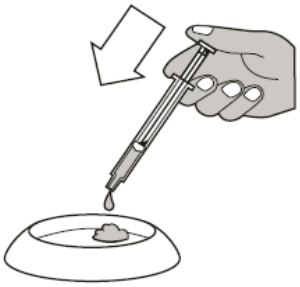
The solution should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a kg-body weight scale.



Push down and turn cap, to open the bottle.
Attach the dosing syringe to the plug-in adapter of the bottle by gently pushing.
Turn the bottle/syringe upside down. Pull the plunger out until the end of the plunger corresponds to your cat´s body weight in kilograms.
Separate the dosing syringe from the bottle.



Push the plunger to empty the contents of the syringe directly into the mouth of the cat …



… or onto a small amount of food.

9. ADVICE ON CORRECT ADMINISTRATION

After administration close bottle tightly with cap.
To avoid contamination, use the provided syringe only to administer Semintra.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions

Shelf life after first opening of the bottle: 6 months.
Do not use after the expiry date stated on the carton and the bottle after EXP.

12. SPECIAL WARNING(S)

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 Semintra which are under anaesthesia.

Due to the mode of action of the veterinary medicinal product, transient hypotension (low blood pressure) 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.

Special precautions to be taken by the person administering the product:
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 accidential 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 (ACEi), 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.

Use during pregnancy or lactation:
The safety of Semintra has not been established in breeding, pregnant or lactating cats.
Do not use during pregancy or laction. See section “Contraindications”.

Interactions
During concomitant therapy with amlodipine at the recommended dose no clinical evidence of hypotension was observed.

Overdose:
After administration of up to 5-fold of the recommended dose for 6 months, no adverse reactions were observed other than those mentioned in section "Adverse reactions".
Administration of the product at overdose (up to 5-fold 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; nitrogen containing waste products in the blood). These effects are unlikely to be observed under clinical conditions.
However, in the event that transient hypotension (low blood pressure) does occur, symptomatic treatment, e.g. fluid therapy, should be provided.

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

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

Any unused medicines or waste materials should not be disposed of via wastewater or household waste but in accordance with local requirements. 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

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency http://www.ema.europa.eu/.

15. OTHER INFORMATION

45 ml plastic bottle, filled with 30 ml.
1 measuring syringe.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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