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

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.

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

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.
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).

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.

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 treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, 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 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 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 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 Semintra.

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

After administration of 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 the product 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

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

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

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 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/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 (30 ml or 100 ml): 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

One HDPE bottle filled with 30 ml or 100 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.
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

Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/12/146/001-002

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13.02.2013
Date of last renewal: 16.01.2018

10. DATE OF REVISION OF THE TEXT

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.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 10 mg/ml oral solution for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 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

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

Special precautions for use in animals
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.

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.

4.6 Adverse reactions (frequency and seriousness)

Mild and transient gastrointestinal signs such as vomiting and diarrhoea associated with product administration have been observed commonly in a clinical study.

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

Effects observed at the recommended treatment dose included mild decreases in red blood cell counts.

In a European clinical field study, adverse events categorised as renal disorder/insufficiency (includes cases of chronic renal failure, elevated creatinine and/or blood urea nitrogen) were recorded in 3.6% of telmisartan-treated cats and 1% of placebo-treated cats.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, 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 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 for the reduction of proteinuria associated with chronic kidney disease (CKD) in cats no clinical evidence of hypotension was observed.

Very limited data are available regarding interactions in cats with hypertension between telmisartan and other medicinal products that lower blood pressure (such as amlodipine) or interfere with the RAAS (such as ARBs or ACEis). The combination of telmisartan with such agents may lead to additive hypotensive effects or may alter renal function.

4.9 Amounts to be administered and administration route

Oral use.

The initial recommended dose is 2 mg telmisartan/kg body weight (0.2 ml/kg body weight).
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.
In cats with hypertension associated with chronic kidney disease the recommended effective dose is not lower than 1 mg/kg.

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 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 Semintra.

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

After administration of up to 2.5 times the initial recommended dose 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 2.5 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 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.
ATCvet 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.

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, organ remodelling and proteinuria. 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 properties

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: 2 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

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.

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)

EU/2/12/146/003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 13.02.2013
Date of last renewal: 16.01.2018

10. DATE OF REVISION OF THE TEXT

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 AND USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

A. MANUFACTURER 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 AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

Not applicable.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

PSURs:

The CVMP agreed that the periodic safety update report (PSUR) cycle would be re-started at 6 months, 12 months and 24 months following authorisation of the extension, as detailed in the CVMP assessment report.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 30 ml and 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 4 mg/ml oral solution for cats
telmisartan

2. STATEMENT OF ACTIVE SUBSTANCES

Telmisartan 4 mg/ml

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

30 ml
100 ml
1 measuring syringe

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months.

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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/2/12/146/001
EU/2/12/146/002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Bottle for 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 4 mg/ml oral solution for cats
telmisartan

2. STATEMENT OF ACTIVE SUBSTANCES

Telmisartan 4 mg/ml

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "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/2/12/146/002

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle for 30 ml

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

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.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 35 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 10 mg/ml oral solution for cats
telmisartan

2. STATEMENT OF ACTIVE SUBSTANCES

Telmisartan 10 mg/ml

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

35 ml
1 measuring syringe

5. TARGET SPECIES

Cats

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 6 months.

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

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/2/12/146/003

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle for 35 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 10 mg/ml oral solution for cats
telmisartan

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Telmisartan 10 mg/ml

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

35 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

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 responsible for batch release
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

Clear, colourless to yellowish viscous solution.

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 "Pregnancy and lactation".
Do not use in cases 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.

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 treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

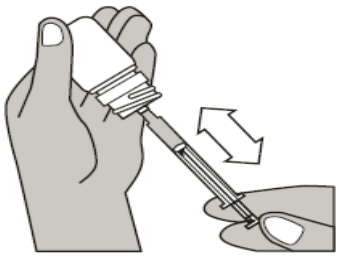
Cats

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

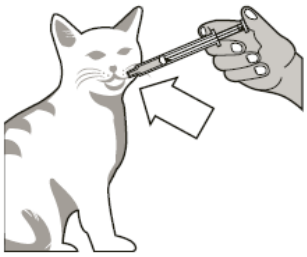
Oral use.

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.

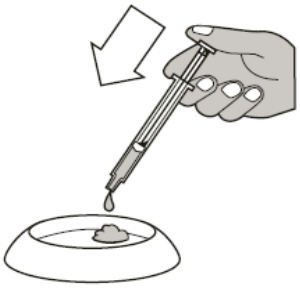
The solution should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a kg-body weight scale.



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 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 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.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after EXP.

Shelf life after first opening of the bottle: 6 months.

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.

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).

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.

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

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.

Overdose (symptoms, emergency procedures, antidotes)
After administration of 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 "Adverse reactions".

Administration of the product 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; nitrogen containing waste products in the blood).

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

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

Pack sizes of one plastic bottle filled with 30 ml or one plastic bottle filled with 100 ml.
1 measuring syringe.
Not all pack sizes may be marketed.

PACKAGE LEAFLET:
Semintra 10 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 responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
GERMANY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 10 mg/ml oral solution for cats
Telmisartan

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

One ml contains:

Telmisartan	10 mg
Benzalkonium chloride	0.1 mg

Clear, colourless to yellowish viscous solution.

4. INDICATION(S)

Treatment of systemic hypertension in cats.

5. CONTRAINDICATIONS

Do not use during pregnancy or lactation. See section "Pregnancy and lactation".
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Mild and transient gastrointestinal signs such as vomiting and diarrhoea associated with product administration have been observed commonly in a clinical study.

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

Effects observed at the recommended treatment dose included mild decreases in red blood cell counts.

In a European clinical field study, adverse events categorised as renal disorder/insufficiency (includes cases of chronic renal failure, elevated creatinine and/or blood urea nitrogen) were recorded in 3.6% of telmisartan-treated cats and 1% of placebo-treated cats.

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

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

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cats

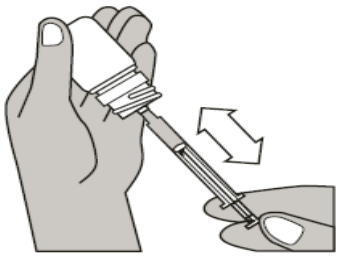
8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Oral use.

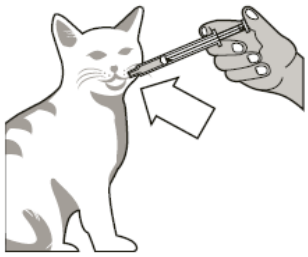
The initial recommended dose is 2 mg telmisartan/kg body weight (0.2 ml/kg body weight).
After 4 weeks, the dosage of telmisartan may be reduced in cats with systolic blood pressure (SBP) of less than 140 mmHg (in 0.5 mg/kg increments) at the discretion of the veterinarian.
If the SBP increases over 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 the "Special warnings" section.
In cats with hypertension associated with chronic kidney disease the recommended effective dose is not lower than 1 mg/kg.

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.

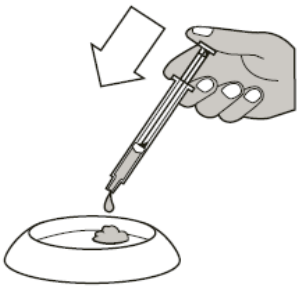
The solution should be given using the measuring syringe provided in the package. The syringe fits onto the bottle and has a ml scale.



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 the amount needed in ml.
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 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 Semintra.

10. WITHDRAWAL PERIOD(S)

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.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the bottle after EXP.

Shelf life after first opening of the bottle: 6 months.

12. SPECIAL WARNING(S)

Special precautions for use in animals
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.

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

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.

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.

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

Interactions with other medicinal products and other forms of interaction
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.

Very limited data are available regarding interactions in cats with hypertension between telmisartan and other medicinal products that lower blood pressure (such as amlodipine) or interfere with RAAS (such as ARBs or ACEis). The combination of telmisartan with such agents may lead to additive hypotensive effects or may alter renal function.

Overdose (symptoms, emergency procedures, antidotes)
After administration of up to 2.5 times the initial recommended dose for 6 months to young adult healthy cats, adverse reactions were consistent with those mentioned in section "Adverse reactions".

Administration of the product at overdose (up to 2.5 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).

In the event that 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

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

Pack size of one plastic bottle filled with 35 ml and one measuring syringe.