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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Telmisartan 4 mg/ml

3. PACKAGE SIZE

30 ml
100 ml
1 measuring syringe

4. TARGET SPECIES

Cats

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

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

9. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton.

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

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

14. MARKETING AUTHORISATION NUMBERS

Vm 04491/5059

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

Info.semintra.com

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (bottle of 100 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 4 mg/ml oral solution for cats

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Telmisartan 4 mg/ml

3. TARGET SPECIES

Cats

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp {mm/yyyy}
Once opened use by ....

7. SPECIAL STORAGE PRECAUTIONS

Keep the bottle in the outer carton

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim/Rhein
GERMANY

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

100 ml

11. INDICATION(S)

12. SPECIAL WARNING(S), IF NECESSARY

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

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

POM-V
To be supplied only on veterinary prescription
For animal treatment only.

15. MARKETING AUTHORISATION NUMBER

Vm 04491/5059

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS (bottle for 30 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Telmisartan 4 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}
Once opened use by ....

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

30 ml

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Semintra 4 mg/ml oral solution for cats
Semintra 10 mg/ml oral solution for cats

2. COMPOSITION

Each ml contains:
Telmisartan 4 mg or 10 mg

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzalkonium chloride	0.1 mg

Clear, colourless to yellowish viscous solution.

3. TARGET SPECIES

Cats

4. INDICATIONS FOR USE

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

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

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 the veterinary medicinal product 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. 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.

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 section “Contraindications”.

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.

Overdose:
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 "Adverse events".

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; nitrogen containing waste products in the blood).

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 products.

7. ADVERSE EVENTS

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 "Special Warnings").

[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 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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

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

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.

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]
4	0.25
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]
4	0.5
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 “Special warnings”.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

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.

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. The expiry date refers to the last day of that month.

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

Once the immediate package is opened, using the shelf-life after first opening, calculate the discard date and record in the space provided.

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.

POM-V

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 04491/5058
Vm 04491/5059

Pack sizes: one plastic bottle filled with 30 ml or 100 ml (4 mg/ml) or one plastic bottle filled with 35 ml (10 mg/ml).
1 measuring syringe.
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

July 2023

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim/Rhein
GERMANY

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
Boehringer Ingelheim Animal Health Belgium SA
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Lietuva
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17. OTHER INFORMATION

The above described information is accessible online using the URL info.semintra.com or the QR code:

Approved 21 July 2023