ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zenalpha 0.5 mg/ml + 10 mg/ml solution for injection for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substances:

Medetomidine hydrochloride 0.5 mg (equivalent to 0.425 mg medetomidine)
Vatinoxan hydrochloride 10 mg (equivalent to 9.2 mg vatinoxan)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	1.8 mg
Propyl parahydroxybenzoate (E216)	0.2 mg
Mannitol (E421)	
Citric acid monohydrate (E330)	
Sodium hydroxide (E524)	
Hydrochloric acid, concentrated (E507)	
Water for injections	

Clear, slightly yellow to yellow or brownish yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

To provide restraint, sedation and analgesia during conduct of non-invasive, non-painful or mildly painful procedures and examinations intended to last no more than 30 minutes.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in animals with cardiovascular disease, respiratory disease or impaired liver or kidney function.
Do not use in animals that are in shock or severely debilitated.
Do not use in animals that have hypoglycaemia or are at risk of developing hypoglycaemia.
Do not use as pre-anaesthetic medicine.
Do not use in cats.

3.4 Special warnings

Nervous or excited dogs with high levels of endogenous catecholamines may exhibit a reduced pharmacological response to alpha-2 adrenoceptor agonists like medetomidine (ineffectiveness). In agitated animals, the onset of sedative/analgesic effects could be slowed, or the depth and duration of effects could be diminished or non-existent. Therefore, the dog should be given the possibility to calm down before initiation of the treatment and rest quietly after administration of the product until evidence of sedation has occurred.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In the absence of available data, treatment of puppies less than 4.5 months of age should be based on a benefit-risk assessment by the responsible veterinarian.

It is recommended that dogs should be fasted in accordance with currently recommended best practice (e.g. 4 – 6 hours for healthy dogs), prior to treatment with this veterinary medicinal product. Water can be given.

Animals should be frequently monitored for cardiovascular function and body temperature during sedation and recovery.

Some cardiovascular effects (e.g. bradycardia, cardiac arrhythmias such as second-degree AV block or ventricular escape complexes) may be observed after treatment.

Over the period of 15–45 minutes post treatment, blood pressure is likely to decrease by approximately 30–50% from pre-treatment levels. Tachycardia with normal blood pressure may be observed from approximately one hour post-treatment and lasting up to six hours. Therefore, frequent monitoring of cardiovascular function should preferably be performed until tachycardia has resolved.

A decrease in body temperature of approximately 1–2 °C is likely to occur after administration.
Once established, hypothermia may persist longer than sedation and analgesia.
To prevent hypothermia, treated animals should be kept warm and at a constant temperature during the procedure and until fully recovered.

Medetomidine can cause apnoea and/or hypoxaemia. This effect is likely to be potentiated if used in combination with opioid medicines. Frequent monitoring of respiratory function should be performed in all cases. It is also advisable to have oxygen readily available, should hypoxaemia be detected or suspected.

Analgesia provided by the veterinary medicinal product may be shorter than the sedative effect.
Additional pain management should be provided as needed.
Spontaneous muscle trembling or twitching can be expected in some dogs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Accidental exposure may cause sedation and changes in blood pressure. Caution is required during treatment administration to avoid accidental self-injection, or skin, eye or mucosal contact. Adequate restraint of the animal is recommended, as some animals may react to the injection (e.g., defence reaction).

Pregnant women should administer the veterinary medicinal product with special caution to avoid self-injection since uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

People with known hypersensitivity to medetomidine hydrochloride, vatinoxan hydrochloride or any of the excipients should administer the veterinary medicinal product with caution.

In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician but DO NOT DRIVE.

In case of skin or mucosal contact, wash the exposed skin immediately after exposure with large amounts of water and remove contaminated clothes that are in direct contact with skin. In case of eye contact, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

To the physician:
The veterinary medicinal product contains medetomidine, an alpha-2 adrenoceptor agonist, in combination with vatinoxan, a peripherally selective alpha-2 adrenoceptor antagonist. Symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Hypothermia[1,3] Bradycardia[1] Tachycardia[1] Arrhythmia[1,2]
Common (1 to 10 animals / 100 animals treated):	Diarrhoea[1] Colitis[1] Muscle tremor[1]
Uncommon (1 to 10 animals / 1 000 animals treated):	Vomiting[1] Nausea[1] Involuntary defecation[1]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Injected sclera[1]

[1] Transient/resolved without treatment.
[2] Such as second-degree AV block, ventricular escape complexes.
[3] External warming was provided when required.
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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy or lactation.

Pregnancy and lactation:

Laboratory studies in rats have not produced any evidence of teratogenic effects. The use is not recommended during pregnancy and lactation.

Fertility:

The safety of the veterinary medicinal product has not been established in dogs intended for breeding. No data are available on the use of vatinoxan in breeding animals.

3.8 Interaction with other medicinal products and other forms of interaction

The use of other central nervous system depressants and/or vasodilating medicines are expected to potentiate the effects of the veterinary medicinal product and an appropriate dose reduction should be made after benefit-risk assessment by the veterinarian.

Due to the rapid recovery from sedation expected with the veterinary medicinal product, routine administration of atipamezole is not indicated after the veterinary medicinal product. The intramuscular administration of atipamezole (30 minutes after the administration of the veterinary medicinal product) has been investigated in a study involving a limited number of animals. As tachycardia was observed in 50% of the animals following the administration of atipamezole, close monitoring of the heart rate during recovery is therefore advised in those cases where administration of atipamezole is deemed clinically necessary.

3.9 Administration routes and dosage

For intramuscular use.

The dose is based on body surface area. The dose will result in administration of 1 mg medetomidine and 20 mg vatinoxan per square metre of body surface area (m^2).

Calculate the dose using 1 mg/m^2 medetomidine or use the dosing table below. Note that the mg/kg dosage decreases as body weight increases.

Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Table 1. Dose volume based on bodyweight

Dog bodyweight	Dose volume
kg	ml
3.5 to 4	0.4
4.1 to 5	0.6
5.1 to 7	0.7
7.1 to 10	0.8
10.1 to 13	1.0
13.1 to 15	1.2
15.1 to 20	1.4
20.1 to 25	1.6
25.1 to 30	1.8
30.1 to 33	2.0
33.1 to 37	2.2
37.1 to 45	2.4
45.1 to 50	2.6
50.1 to 55	2.8
55.1 to 60	3.0

60.1 to 65	3.2
65.1 to 70	3.4
70.1 to 80	3.6
> 80	3.8

Re-administration of the veterinary medicinal product during the same procedure has not been evaluated and therefore the veterinary medicinal product should not be re-administered during the same procedure.

The number of permissible stopper broachings is limited to a maximum of 15.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

The veterinary medicinal product given 3 and 5 times the recommended dose, showed a slightly prolonged sedation and greater degree of reduction in mean arterial pressure and rectal temperature. Overdose can increase incidence of sinus tachycardia during recovery.

Atipamezole can be administered to reverse the central nervous system effects and most of the cardiovascular effects of medetomidine, excluding hypotension. Appropriate cardiopulmonary support should be initiated if required.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QN05CM99

4.2 Pharmacodynamics

Medetomidine is a potent and selective alpha-2 adrenoceptor agonist that inhibits the release of noradrenaline from noradrenergic neurons and produces sedation and analgesia. These effects are dose dependent in depth and duration. Medetomidine is a racemic mixture containing the active enantiomer dexmedetomidine and the inactive enantiomer levomedetomidine. Within the central nervous system, sympathetic neurotransmission is inhibited and the level of consciousness decreases. Respiratory rate and body temperature can also decrease. In the periphery, medetomidine stimulates alpha-2 adrenoceptors within vascular smooth muscle which induces vasoconstriction and hypertension, resulting in decreased heart rate and cardiac output. Dexmedetomidine also induces a number of other alpha-2 adrenoceptor mediated effects, which include piloerection, depression of motor and secretory functions of the gastrointestinal tract, diuresis and hyperglycaemia.

Vatinoxan is a peripherally selective alpha-2 adrenoceptor antagonist which poorly penetrates the central nervous system. Vatinoxan is administered as the active (RS) diastereomer. By limiting its effects to peripheral organ systems, vatinoxan will prevent or attenuate the cardiovascular and other effects of dexmedetomidine outside the central nervous system when administered simultaneously with the alpha-2 adrenoceptor agonist. The central effects of dexmedetomidine remain unaltered, although vatinoxan will reduce the duration of sedation and analgesia induced by dexmedetomidine, predominantly by increasing the clearance of the latter via improving the cardiovascular function. Vatinoxan stimulates insulin release and counteracts medetomidine’s hyperglycaemic effects.

The safety and efficacy of the veterinary medicinal product was tested in a multi-centre clinical study, using 223 client-owned dogs. Dogs requiring a non-invasive, non-painful or mildly painful procedure or examination were treated with either the recommended dose of the veterinary medicinal product (test group), or dexmedetomidine (control group). Procedures included: radiographic examination or diagnostic imaging, ear examination and treatment, eye examination and treatment, anal sac treatment, dermatological examination and procedures, orthopaedic examination, dental examination and biopsy, fine needle aspiration/superficial biopsy, drain seroma or abscess, nail trimming, coat grooming and venous blood draw. One hundred and ten dogs received the test product. In this group, sedation sufficient to perform the procedure occurred on average in 14 minutes. Although duration of clinically-useful sedation varies substantially between individuals and intended procedure, 73% of test group cases had at least 30 minutes duration of sedation and the procedure was completed successfully in 94.5% of cases. Test group mean heart rate remained within the normal range (60–140 beats per minute) at all times after administration; however, 22% of dogs displayed tachycardia at some time point(s) after treatment (range 140–240 beats per minute). In the dexmedetomidine-treated control group, the average time to onset of sedation was 18 minutes and sedation lasted for at least 30 minutes in 80% of dogs. The procedure was completed successfully in 90.1% of control group cases.

4.3 Pharmacokinetics

After intramuscular administration of a pilot formulation of medetomidine (1 mg/m^2) + vatinoxan (30 mg/m^2), both medetomidine and vatinoxan were rapidly and highly absorbed from the injection site. Maximal plasma concentration was reached at 12.6 ± 4.7 (mean ± standard deviation) minutes and 17.5 ± 7.4 minutes for dexmedetomidine (the active enantiomer of medetomidine) and vatinoxan, respectively. Vatinoxan increased the volume of distribution and the clearance of dexmedetomidine. Thus, the clearance of dexmedetomidine was increased two-fold when given in combination with vatinoxan. The same phenomena were also seen with intravenous administration.
Concentrations of dexmedetomidine and vatinoxan in cerebrospinal fluid (CSF) were measured after intravenous administration of the final formulation of the veterinary medicinal product. Plasma unbound fraction : CSF ratio was approximately 50:1 for vatinoxan and 1:1 for dexmedetomidine.

Medetomidine plasma protein binding is high (85–90%). Medetomidine is mainly oxidised in the liver, a smaller amount undergoes methylation in the kidneys, and excretion is mainly via urine. Vatinoxan plasma protein binding is approximately 70%. Low levels are detectable in the central nervous system. Vatinoxan is metabolised to a very limited extent in the dog. Only a small amount (< 5%) of vatinoxan dose has been found to be excreted via the urine. This suggests that vatinoxan is most likely eliminated in the faeces, although no data are available to confirm this.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 3 months.

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Clear type I glass vials closed with coated bromobutyl rubber stopper with an aluminium seal and a flip-top cap.

Pack sizes:
Cardboard box with 1 vial of 10 ml.
Cardboard box with 5 boxes of 1 vial of 10 ml.
Cardboard box with 10 boxes of 1 vial of 10 ml.

Not all pack sizes may be marketed.

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

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Vetcare Oy

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/21/279/001-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 15/12/2021

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zenalpha 0.5 mg/ml + 10 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
0.5 mg medetomidine hydrochloride (equivalent to 0.425 mg medetomidine)
10 mg vatinoxan hydrochloride (equivalent to 9.2 mg vatinoxan)

3. PACKAGE SIZE

10 ml
5 x 10 ml
10 x 10 ml

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For intramuscular use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 3 months.

9. SPECIAL STORAGE PRECAUTIONS

Keep the vial in the outer carton 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 OF THE MARKETING AUTHORISATION HOLDER

Vetcare Oy

14. MARKETING AUTHORISATION NUMBERS

EU/2/21/279/001-003

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zenalpha

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

0.5 mg/ml + 10 mg/ml

10 ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 3 months.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Zenalpha 0.5 mg/ml +10 mg/ml solution for injection for dogs

2. Composition

1 ml contains:

Active substances:

Medetomidine hydrochloride	0.5 mg (equivalent to 0.425 mg medetomidine)
Vatinoxan hydrochloride	10 mg (equivalent to 9.2 mg vatinoxan)

Excipients:

Methyl parahydroxybenzoate (E 218)	1.8 mg
Propyl parahydroxybenzoate (E 216)	0.2 mg

Clear, slightly yellow to yellow or brownish yellow solution.

3. Target species

Dogs.

4. Indications for use

To provide restraint, sedation and analgesia during conduct of non-invasive, non-painful or mildly painful procedures and examinations intended to last no more than 30 minutes.

5. Contraindications

Do not use in cases of hypersensitivity to the active substances or to any of the excipients.
Do not use in animals with cardiovascular disease, respiratory disease or impaired liver or kidney function.
Do not use in animals that are in shock or severely debilitated.
Do not use in animals that have hypoglycaemia or are at risk of developing hypoglycaemia.
Do not use as pre-anaesthetic medicine.
Do not use in cats.

6. Special warnings

Special warnings:
In the absence of available data, treatment of puppies less than 4.5 months of age should be based on a benefit-risk assessment by the responsible veterinarian.

It is recommended that dogs should be fasted in accordance with currently recommended best practice (e.g. 4 – 6 hours for healthy dogs), prior to treatment with this veterinary medicinal product. Water can be given.

Animals should be frequently monitored for cardiovascular function and body temperature during sedation and recovery.

Some cardiovascular effects (e.g. bradycardia, cardiac arrhythmias such as second degree AV block or ventricular escape complexes) may be observed after treatment.

Over the period of 15–45 minutes post treatment, blood pressure is likely to decrease by approximately 30–50% from pre-treatment levels. Tachycardia with normal blood pressure may be observed from approximately one hour post-treatment and lasting up to six hours. Therefore, frequent monitoring of cardiovascular function should preferably be performed until tachycardia has resolved.

A decrease in body temperature of approximately 1–2 °C is likely to occur after administration. Once established, hypothermia may persist longer than sedation and analgesia.
To prevent hypothermia, treated animals should be kept warm and at a constant temperature during the procedure and until fully recovered.

Medetomidine can cause apnoea and/or hypoxaemia. This effect is likely to be potentiated if used in combination with opioid medicines. Frequent monitoring of respiratory function should be performed in all cases. It is also advisable to have oxygen readily available, should hypoxaemia be detected or suspected.

Analgesia provided by the veterinary medicinal product may be shorter than the sedative effect. Additional pain management should be provided as needed.

Spontaneous muscle trembling or twitching can be expected in some dogs.

Special precautions for safe use in the target species:
Nervous or excited dogs with high levels of endogenous catecholamines may exhibit a reduced pharmacological response to alpha-2 adrenoceptor agonists like medetomidine (ineffectiveness). In agitated animals, the onset of sedative/analgesic effects could be slowed, or the depth and duration of effects could be diminished or non-existent. Therefore, the dog should be given the possibility to calm down before initiation of the treatment and rest quietly after administration of the product until evidence of sedation has occurred.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental exposure may cause sedation and changes in blood pressure. Caution is required during treatment administration to avoid accidental self-injection, or skin, eye or mucosal contact. Adequate restraint of the animal is recommended, as some animals may react to the injection (e.g., defence reaction).

Pregnant women should administer the veterinary medicinal product with special caution to avoid self-injection since uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

People with known hypersensitivity to medetomidine hydrochloride, vatinoxan hydrochloride or any of the excipients should administer the veterinary medicinal product with caution.

In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician but DO NOT DRIVE.

In case of skin or mucosal contact, wash the exposed skin immediately after exposure with large amounts of water and remove contaminated clothes that are in direct contact with skin. In case of eye contact, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

To the physician: The veterinary medicinal product contains medetomidine, an alpha-2 adrenoceptor agonist, in combination with vatinoxan, a peripherally selective alpha-2 adrenoceptor antagonist.

Symptoms after absorption may involve clinical effects including dose-dependent sedation, respiratory depression, bradycardia, hypotension, a dry mouth, and hyperglycaemia. Ventricular arrhythmias have also been reported. Respiratory and haemodynamic symptoms should be treated symptomatically.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation. Laboratory studies in rats have not produced any evidence of teratogenic effects. The use is not recommended during pregnancy and lactation.

Fertility:
The safety of the veterinary medicinal product has not been established in dogs intended for breeding. No data are available on the use of vatinoxan in breeding animals.

Interaction with other medicinal products and other forms of interaction:
The use of other central nervous system depressants and/or vasodilating medicines are expected to potentiate the effects of the veterinary medicinal product and an appropriate dose reduction should be made after benefit-risk assessment by the veterinarian.

Due to the rapid recovery from sedation expected with the veterinary medicinal product, routine administration of atipamezole is not indicated after the veterinary medicinal product. The intramuscular administration of atipamezole (30 minutes after the administration of the veterinary medicinal product) has been investigated in a study involving a limited number of animals. As tachycardia was observed in 50% of the animals following the administration of atipamezole, close monitoring of the heart rate during recovery is therefore advised in those cases where administration of atipamezole is deemed clinically necessary.

Overdose:
The veterinary medicinal product given 3 and 5 times the recommended dose, showed a slightly prolonged sedation and greater degree of reduction in mean arterial pressure and rectal temperature. Overdose can increase incidence of sinus tachycardia during recovery.

Atipamezole can be administered to reverse the central nervous system effects and most of the cardiovascular effects of medetomidine, excluding hypotension. Appropriate cardiopulmonary support should be initiated if required.

7. Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Hypothermia (low body temperature)[1,3] Bradycardia (slow heart rate)[1] Tachycardia (rapid heart rate)[1] Cardiac arrhythmias (irregular heart rate)[1,2]
Common (1 to 10 animals / 100 animals treated):	Diarrhoea[1] Colitis (inflammation of the colon)[1] Muscle tremor[1]
Uncommon (1 to 10 animals / 1 000 animals treated):	Vomiting[1] Nausea[1] Involuntary defecation[1]
Very rare	Injected sclera (bloodshot eyes)[1]

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

[1] Transient/resolved without treatment.
[2] Such as second-degree AV block, ventricular escape complexes.
[3] External warming was provided when required.

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 marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

For intramuscular use.

The dose is based on body surface area. The dose will result in administration of 1 mg medetomidine and 20 mg vatinoxan per square metre of body surface area (m^2).

Calculate the dose using 1 mg/m^2 medetomidine or use the dosing table below. Note that the mg/kg dosage decreases as body weight increases.

To ensure a correct dosage, bodyweight should be determined as accurately as possible.

Table 1. Dose volume based on bodyweight

Dog bodyweight	Dose volume
kg	ml
3.5 to 4	0.4
4.1 to 5	0.6
5.1 to 7	0.7
7.1 to 10	0.8
10.1 to 13	1.0
13.1 to 15	1.2
15.1 to 20	1.4
20.1 to 25	1.6
25.1 to 30	1.8
30.1 to 33	2.0
33.1 to 37	2.2
37.1 to 45	2.4
45.1 to 50	2.6
50.1 to 55	2.8
55.1 to 60	3.0
60.1 to 65	3.2
65.1 to 70	3.4
70.1 to 80	3.6
> 80	3.8

Re-administration of the veterinary medicinal product during the same procedure has not been evaluated and therefore the veterinary medicinal product should not be re-administered during the same procedure.

The number of permissible stopper broachings is limited to a maximum of 15.

9. Advice on correct administration

Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Keep the vial in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 3 months.

12. Special precautions for disposal

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

EU/2/21/279/001-003

Pack sizes:
Cardboard box with 1 vial of 10 ml.
Cardboard box with 5 boxes of 1 vial of 10 ml.
Cardboard box with 10 boxes of 1 vial of 10 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder:
Vetcare Oy, P.O. Box 99, 24101 Salo, Finland

Manufacturer responsible for batch release:
Apotek Produktion & Laboratorier AB, Formvägen 5B, SE-90621 Umeå, Sweden
Eurovet Animal Health BV, Handelsweg 25, NL-5531 AE Bladel, The Netherlands

Local representatives and contact details to report suspected adverse events:

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

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