**ANNEX I**

**SUMMARY OF PRODUCT CHARACTERISTICS**

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedator 1 mg/ml solution for injection for dogs and cats.
Sweden/Finland: Sedator vet 1 mg/ml solution for injection for dogs and cats.
Norway: Medodin vet 1 mg/ml solution for injection for dogs and cats.

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substances:**
Medetomidine hydrochloride 1 mg
(equivalent to 0.85 mg medetomidine)

FR: Medetomidine (as hydrochloride) 0.85 mg
(equivalent to 1 mg medetomidine hydrochloride)

**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 mg |
| Propyl parahydroxybenzoate | 0.2 mg |
| Sodium chloride | |
| Hydrochloric acid (for pH adjustment) | |
| Sodium hydroxide (for pH adjustment) | |
| Water for injections | |

Clear and colourless sterile aqueous solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dogs and cats.

### 3.2 Indications for use for each target species

In dogs and cats:
Sedation to facilitate handling. Premedication prior to general anaesthesia.

In cats:
In combination with ketamine for general anaesthesia for minor surgical procedures of short duration.

### 3.3 Contraindications

Do not use in animals with:

- severe cardiovascular disease or respiratory diseases or impaired liver or kidney function,
- mechanical disturbances of the gastro-intestinal tract (torsio ventriculi, incarcerations, oesophageal obstructions),
- diabetes mellitus,
- state of shock, emaciation or serious debilitation.

Do not use concomitantly with sympathomimetic amines.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.
See also section 3.7.

### 3.4 Special warnings

Medetomidine may not provide analgesia throughout the entire period of sedation, therefore consideration should be given to providing additional analgesia for painful procedures.

### 3.5 Special precautions for use

Special precautions for safe use in the target species:
A clinical examination should be carried out in all animals before the use of veterinary medicinal products for sedation and/or general anaesthesia. Higher doses of medetomidine should be avoided in large breed dogs. Care should be taken when combining medetomidine with other anaesthetics or sedatives (e.g. ketamine, thiopental, propofol, halothane), because of its marked anaesthetic sparing effects. The dose of the anaesthetic should be reduced accordingly and titrated to response due to considerable variability in requirements between patients. Before using any combinations, the warnings and contra-indications in the product literature for the other veterinary medicinal products should be observed.
Animals should be fasted 12 hours before anaesthesia.
The animal should be placed in a calm and quiet surrounding to let the sedation gain its maximum effect. This takes about 10 – 15 minutes. One should not start any procedure or give other medicines before maximum sedation is reached.
Treated animals should be kept warm and at a constant temperature, both during the procedure and recovery. The eyes should be protected by a suitable lubricant.
Nervous, aggressive or excited animals should be given the possibility to calm down before initiation of treatment.
Sick and debilitated dogs and cats should only be premedicated with medetomidine before induction and maintenance of general anaesthesia based on a risk-benefit assessment.
Care should be taken with use of medetomidine in animals with cardiovascular disease, or which are elderly or in general poor health. Liver and kidney function should be evaluated prior to use.
Medetomidine may cause respiratory depression and under these circumstances, manual ventilation and oxygen may be administered.
To reduce the recovery time following anaesthesia or sedation the effect of the veterinary medicinal product can be reversed by administration of an alpha-2 antagonist e.g. atipamezole or yohimbine. As ketamine alone can elicit cramps, alpha-2 antagonists should be administered not before 30-40 min. after ketamine. For dosage directions, see section 3.10.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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 as sedation and changes in blood pressure may occur.
Avoid skin, eye or mucosal contact.
Wash the exposed skin immediately after exposure with large amounts of water.
Remove contaminated clothes that are in direct contact with skin.
In case of accidental eye contact, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

If pregnant women handle the veterinary medicinal product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.
To the physician: Medetomidine is an alpha2-adrenoreceptor agonist, 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 and cats

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated): | Pulmonary oedema |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Bradycardia, Heart block 1st degree, Heart block 2nd degree, Extrasystole, Hypertension [a], Decreased cardiac output, Circulatory depression [b]<br>Respiratory depression [b]<br>Cyanosis, Hypothermia<br>Vomiting [c]<br>Increased sensitivity to sound, Muscle tremor<br>Polyuria<br>Hyperglycaemia [d]<br>Injection site pain |
| Undetermined frequency (cannot be estimated from the available data): | Vasoconstriction of coronary artery |

[a] Blood pressure will increase initially after administration and then return to normal, or slightly below normal.
[b] Manual ventilation and an oxygen supplement may be indicated. Atropine may increase the cardiac rate.
[c] In some dogs and most cats within 5-10 minutes of injection, in cats also on recovery.
[d] Reversible, due to depression of insulin secretion.

Dogs with a body weight of less than 10 kg may show the undesirable effects mentioned above more often.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also the package leaflet for respective contact details.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Do not use during pregnancy and lactation.

### 3.8 Interaction with other medicinal products and other forms of interaction

The concomitant use of other CNS depressants should be expected to potentiate the effect of either active substance. Appropriate dose adjustments should be made.
Medetomidine has marked anaesthetic sparing effects. See also section 3.5.
The effects of medetomidine may be antagonized by administration of atipamezole or yohimbine. See also section 3.10.

### 3.9 Administration routes and dosage

Dogs: Intramuscular or intravenous use.
Cats: Intramuscular use.
Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

Dogs:
For sedation the veterinary medicinal product should be administered at the rate of 750 µg medetomidine hydrochloride i.v. or 1000 µg medetomidine hydrochloride i.m. per square meter of body surface. Use the table below to determine the correct dosage on the basis of body weight:
Maximal effect is obtained within 15-20 minutes. Clinical effect is dose-dependent, lasting from 30 – 180 minutes.

Dosages of the veterinary medicinal product in ml and corresponding amount of medetomidine hydrochloride in µg /kg bw:

| body weight (kg) | intravenous injection (ml) | corresponding to (µg/kg bw) | intramuscular injection (ml) | corresponding to (µg/kg bw) |
|---|---|---|---|---|
| 1 | 0,08 | 80.0 | 0,10 | 100.0 |
| 2 | 0,12 | 60.0 | 0,16 | 80.0 |
| 3 | 0,16 | 53.3 | 0,21 | 70.0 |
| 4 | 0,19 | 47.5 | 0,25 | 62.5 |
| 5 | 0,22 | 44.0 | 0,30 | 60.0 |
| 6 | 0,25 | 41.7 | 0,33 | 55.0 |
| 7 | 0,28 | 40.0 | 0,37 | 52.9 |
| 8 | 0,30 | 37.5 | 0,40 | 50.0 |
| 9 | 0,33 | 36.7 | 0,44 | 48.9 |
| 10 | 0,35 | 35.0 | 0,47 | 47.0 |
| 12 | 0,40 | 33.3 | 0,53 | 44.2 |
| 14 | 0,44 | 31.4 | 0,59 | 42.1 |
| 16 | 0,48 | 30.0 | 0,64 | 40.0 |
| 18 | 0,52 | 28.9 | 0,69 | 38.3 |
| 20 | 0,56 | 28.0 | 0,74 | 37.0 |
| 25 | 0,65 | 26.0 | 0,86 | 34.4 |
| 30 | 0,73 | 24.3 | 0,98 | 32.7 |
| 35 | 0,81 | 23.1 | 1,08 | 30.9 |
| 40 | 0,89 | 22.2 | 1,18 | 29.5 |
| 50 | 1,03 | 20.6 | 1,37 | 27.4 |
| 60 | 1,16 | 19.3 | 1,55 | 25.8 |
| 70 | 1,29 | 18.4 | 1,72 | 24.6 |
| 80 | 1,41 | 17.6 | 1,88 | 23.5 |

| | | | | |
|---|---|---|---|---|
| 90 | 1,52 | 16.9 | 2,03 | 22.6 |
| 100 | 1,63 | 16.3 | 2,18 | 21.8 |

For premedication the veterinary medicinal product should be administered at a dosage of 10-40 µg medetomidine hydrochloride per kg body weight, corresponding to 0.1-0.4 ml of the veterinary medicinal product per 10 kg body weight. The exact dose depends on the combination of drugs used and the dosage(s) of the other drug(s). The dose should furthermore be adjusted to the type of surgery, length of procedure and patient temperament and weight. Premedication with medetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect. Before using any combinations, product literature for the other veterinary medicinal products should be observed. See also section 3.5.

Cats:
For moderate-deep sedation and restraint of cats the veterinary medicinal product should be administered at a dosage of 50 – 150 µg medetomidine hydrochloride /kg bw (corresp. to 0.05 – 0.15 ml of the veterinary medicinal product / kg bw).
For anaesthesia the veterinary medicinal product should be administered at a dosage of 80 µg medetomidine hydrochloride / kg bw (corresp. to 0.08 ml of the veterinary medicinal product / kg bw) and 2.5 to 7.5 mg ketamine / kg bw. Using this dosage anaesthesia occurs within 3 – 4 minutes and is apparent for 20 – 50 minutes. For longer lasting procedures administration has to be repeated by using ½ of the initial dose (i.e. 40 µg medetomidine hydrochloride (corresp. to 0.04 ml of the veterinary medicinal product / kg bw) and 2.5 - 3.75 mg ketamine / kg bw) or 3.0 mg ketamine / kg bw alone. Alternatively, for longer lasting procedures anaesthesia may be extended by use of the inhalation agents isoflurane or halothane, with oxygen or oxygen/nitrous oxide. See section 3.5

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

In the case of overdose the main signs are prolonged anaesthesia or sedation. In some cases cardio-respiratory effects may occur. For treatment of these cardio-respiratory effects of an overdose it is recommended to administer an alpha-2 antagonist e.g. atipamezole or yohimbine, provided that reversal of sedation is not dangerous to the patient (atipamezole does not reverse the effects of ketamine which may cause seizures in dogs and elicit cramps in cats when used alone). Alpha-2 antagonists should be administered not before 30-40 min. after ketamine.
Use atipamezole hydrochloride 5 mg/ml intramuscularly in the dog in the same volume as the veterinary medicinal product, in the cat use half the volume. The required dose of atipamezole hydrochloride corresponds in dogs to the 5-fold dose of the medetomidine hydrochloride dose in mg administered before and in cats to the 2.5-fold dose.
If it is imperative to reverse bradycardia but maintain sedation, atropine may be used.

### 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

### 3.12 Withdrawal periods

Not applicable.

## 4. PHARMACOLOGICAL INFORMATION

### 4.1 ATCvet code: QN05CM91

### 4.2 Pharmacodynamics

The active ingredient of the veterinary medicinal product is (R,S)-4-[1-(2,3-dimethylphenyl)-ethyl)]-imidazole-hydrochloride (INN: Medetomidine), a sedative compound with analgesic and myorelaxing

properties. Medetomidine is a selective, specific and highly efficacious alpha-2-receptor agonist. The activation of alpha-2 receptors leads to a decrease in release and turnover of norepinephrine in the central nervous system, leading to sedation, analgesia and bradycardia. In the periphery medetomidine causes vasoconstriction via stimulation of postsynaptic alpha-2 adrenoceptors, leading to a transient arterial hypertension. Within 1 – 2 hours arterial blood pressure falls back to normotension or slight hypotension. The respiratory rate may be transiently decreased. Depth and duration of sedation and analgesia are dose related. Profound sedation and recumbency, with reduced sensitivity to environmental stimuli (sounds, etc.), are seen with medetomidine. Medetomidine acts synergistically with ketamine and opiates, such as fentanyl, leading to better anaesthesia. The amount of volatile anaesthetics, such as halothane, will be reduced by medetomidine. Besides its sedative, analgesic and myo-relaxing properties, medetomidine also exerts hypothermic and mydriatic effects, inhibits salivation and decreases intestinal motility.

### 4.3 Pharmacokinetics

After intramuscular administration medetomidine is rapidly and nearly completely absorbed from the injection site and pharmacokinetics is very similar to intravenous administration. Maximal plasma concentrations are reached within 15 and 20 minutes. Plasma half-life is considered to be 1.2 hours in the dog and 1.5 hours in the cat. Medetomidine is mainly oxidised in the liver, a smaller amount undergoes methylation in the kidneys. Metabolites will be excreted mainly via urine.

## 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: 28 days.

### 5.3 Special precautions for storage

Do not freeze.

### 5.4 Nature and composition of immediate packaging

Cardboard box with 1 clear glass type I vial of 5, 10 or 20 ml, with a teflon coated halogenated type I rubber stopper and aluminium cap.
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

## 7. MARKETING AUTHORISATION NUMBER(S)

## 8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 27/10/2011.

## 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 III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**CARDBOARD BOX**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedator 1 mg/ml, solution for injection

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

**Active substance:**
Medetomidine hydrochloride 1 mg
(equivalent to 0.85 mg medetomidine)

FR: Medetomidine (as hydrochloride) 0.85 mg
(equivalent to 1 mg medetomidine hydrochloride)

## 3. PACKAGE SIZE

5ml
10 ml
20 ml

## 4. TARGET SPECIES

Dogs and cats.


## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Dogs: Intramuscular or intravenous use.
Cats: Intramuscular use.

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the immediate packaging: 28 days.

Once broached use by: __/__/____.

## 9. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

## 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

[Company logo]

## 14. MARKETING AUTHORISATION NUMBERS

## 15. BATCH NUMBER

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

**GLASS VIAL**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sedator

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

**Active substance:**
Medetomidine hydrochloride 1 mg
(equivalent to 0.85 mg medetomidine)

FR: Medetomidine (as hydrochloride) 0.85 mg(equivalent to 1 mg medetomidine hydrochloride)

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET

## 1. Name of the veterinary medicinal product

Sedator 1 mg/ml, solution for injection for dogs and cats.

## 2. Composition

Each ml contains:

**Active substance:**
Medetomidine hydrochloride 1 mg
(equivalent to 0.85 mg medetomidine)

FR: Medetomidine (as hydrochloride) 0.85 mg
(equivalent to 1 mg medetomidine hydrochloride)

**Excipients:**
Methyl parahydroxybenzoate 1 mg
Propyl parahydroxybenzoate 0.2 mg

Clear and colourless sterile aqueous solution.

## 3. Target species

Dogs and cats.

## 4. Indications for use

In dogs and cats:
Sedation to facilitate handling. Premedication prior to general anaesthesia.

In cats:
In combination with ketamine for general anaesthesia for minor surgical procedures of short duration.

## 5. Contraindications

Do not use in animals with:
- severe cardiovascular disease or respiratory diseases or impaired liver or kidney function,
- mechanical disturbances of the gastro-intestinal tract (torsion of the stomach, incarcerations, oesophageal obstructions),
- diabetes mellitus,
- state of shock, emaciation or serious debilitation.

Do not use concomitantly with sympathomimetic amines.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.

## 6. Special warnings

Special warnings:

Medetomidine may not provide analgesia throughout the entire period of sedation, therefore consideration should be given to providing additional analgesia for painful procedures.

Special precautions for safe use in the target species:
A clinical examination should be carried out in all animals before the use of veterinary medicinal products for sedation and/or general anaesthesia. Higher doses of medetomidine should be avoided in large breed dogs. Care should be taken when combining medetomidine with other anaesthetics or sedatives (e.g. ketamine, thiopental, propofol, halothane), because of its marked anaesthetic sparing effects. The dose of the anaesthetic should be reduced accordingly and titrated to response due to considerable variability in requirements between patients. Before using any combinations, the warnings and contra-indications in the product literature for the other veterinary medicinal products should be observed.
Animals should be fasted 12 hours before anaesthesia.
The animal should be placed in a calm and quiet surrounding to let the sedation gain its maximum effect. This takes about 10 – 15 minutes. One should not start any procedure or give other medicines before maximum sedation is reached.
Treated animals should be kept warm and at a constant temperature, both during the procedure and recovery. The eyes should be protected by a suitable lubricant.
Nervous, aggressive or excited animals should be given the possibility to calm down before initiation of treatment.
Sick and debilitated dogs and cats should only be premedicated with medetomidine before induction and maintenance of general anaesthesia based on a risk-benefit assessment.
Care should be taken with use of medetomidine in animals with cardiovascular disease, or which are elderly or in general poor health. Liver and kidney function should be evaluated prior to use.
Medetomidine may cause respiratory depression and under these circumstances, manual ventilation and oxygen may be administered.
To reduce the recovery time following anaesthesia or sedation the effect of the veterinary medicinal product can be reversed by administration of an alpha-2 antagonist e.g. atipamezole or yohimbine. As ketamine alone can elicit cramps, alpha-2 antagonists should be administered not before 30-40 min. after ketamine. For dosage directions, see “overdose” section.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In the 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 as sedation and changes in blood pressure may occur.
Avoid skin, eye or mucosal contact.
Wash the exposed skin immediately after exposure with large amounts of water.
Remove contaminated clothes that are in direct contact with skin.
In case of accidental eye contact, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.
If pregnant women handle the veterinary medicinal product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.
To the physician: Medetomidine is an alpha2-adrenoreceptor agonist, 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 and lactation.
Do not use during pregnancy and lactation.
Interaction with other medicinal products and other forms of interaction:
The concomitant use of other CNS depressants should be expected to potentiate the effect of either active substance. Appropriate dose adjustments should be made.
Medetomidine has marked anaesthetic sparing effects. See also the second part of this section.

The effects of medetomidine may be antagonized by administration of atipamezole or yohimbine. See also the following part of this section.

Overdose:
In the case of overdose the main signs are prolonged anaesthesia or sedation. In some cases cardio-respiratory effects may occur. For treatment of these cardio-respiratory effects of an overdose it is recommended to administer an alpha-2 antagonist e.g. atipamezole or yohimbine, provided that reversal of sedation is not dangerous to the patient (atipamezole does not reverse the effects of ketamine which may cause seizures in dogs and elicit cramps in cats when used alone). Alpha-2 antagonists should be administered not before 30-40 min. after ketamine.
Use atipamezole hydrochloride 5 mg/ml intramuscularly in the dog in the same volume as the veterinary medicinal product, in the cat use half the volume. The required dose of atipamezole hydrochloride corresponds in dogs to the 5-fold dose of the medetomidine hydrochloride dose in mg administered before and in cats to the 2.5-fold dose.
If it is imperative to reverse bradycardia but maintain sedation, atropine may be used.

<Special restrictions for use and special conditions for use:>

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

## 7. Adverse events

Dogs and cats:

| | |
|---|---|
| Rare<br>(1 to 10 animals / 10,000 animals treated): | Pulmonary oedema |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Bradycardia, Heart block 1st degree, Heart block 2nd degree, Extrasystole, Hypertension [a], Decreased cardiac output, Circulatory depression [b]<br>Respiratory depression [b]<br>Cyanosis, Hypothermia<br>Vomiting [c]<br>Increased sensitivity to sound, Muscle tremor<br>Polyuria<br>Hyperglycaemia [d]<br>Injection site pain |
| Undetermined frequency (cannot be estimated from the available data): | Vasoconstriction of coronary artery |

[a] Blood pressure will increase initially after administration and then return to normal, or slightly below normal.
[b] Manual ventilation and an oxygen supplement may be indicated. Atropine may increase the cardiac rate.
[c] In some dogs and most cats within 5-10 minutes of injection, in cats also on recovery.
[d] Reversible due to depression of insulin secretion.

Dogs with a body weight of less than 10 kg may show the undesirable effects mentioned above more often.

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 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, routes and method of administration

Dogs: Intramuscular or intravenous use.
Cats: Intramuscular use.
Use of an appropriately graduated syringe is recommended to ensure accurate dosing when administering small volumes.

Dogs:
For sedation the veterinary medicinal should be administered at the rate of 750 µg medetomidine hydrochloride i.v. or 1000 µg medetomidine hydrochloride i.m. per square meter of body surface. Use the table below to determine the correct dosage on the basis of body weight:
Maximal effect is obtained within 15-20 minutes. Clinical effect is dose-dependent, lasting from 30 – 180 minutes.

The veterinary medicinal product dosages in ml and corresponding amount of medetomidine hydrochloride in µg /kg bw:

| body weight (kg) | intravenous injection (ml) | corresponding to (µg/kg bw) | intramuscular injection (ml) | corresponding to (µg/kg bw) |
|---|---|---|---|---|
| 1 | 0,08 | 80.0 | 0,10 | 100.0 |
| 2 | 0,12 | 60.0 | 0,16 | 80.0 |
| 3 | 0,16 | 53.3 | 0,21 | 70.0 |
| 4 | 0,19 | 47.5 | 0,25 | 62.5 |
| 5 | 0,22 | 44.0 | 0,30 | 60.0 |
| 6 | 0,25 | 41.7 | 0,33 | 55.0 |
| 7 | 0,28 | 40.0 | 0,37 | 52.9 |
| 8 | 0,30 | 37.5 | 0,40 | 50.0 |
| 9 | 0,33 | 36.7 | 0,44 | 48.9 |
| 10 | 0,35 | 35.0 | 0,47 | 47.0 |
| 12 | 0,40 | 33.3 | 0,53 | 44.2 |
| 14 | 0,44 | 31.4 | 0,59 | 42.1 |
| 16 | 0,48 | 30.0 | 0,64 | 40.0 |
| 18 | 0,52 | 28.9 | 0,69 | 38.3 |
| 20 | 0,56 | 28.0 | 0,74 | 37.0 |
| 25 | 0,65 | 26.0 | 0,86 | 34.4 |
| 30 | 0,73 | 24.3 | 0,98 | 32.7 |
| 35 | 0,81 | 23.1 | 1,08 | 30.9 |
| 40 | 0,89 | 22.2 | 1,18 | 29.5 |
| 50 | 1,03 | 20.6 | 1,37 | 27.4 |
| 60 | 1,16 | 19.3 | 1,55 | 25.8 |
| 70 | 1,29 | 18.4 | 1,72 | 24.6 |
| 80 | 1,41 | 17.6 | 1,88 | 23.5 |

| | | | | |
|---|---|---|---|---|
| 90 | 1,52 | 16.9 | 2,03 | 22.6 |
| 100 | 1,63 | 16.3 | 2,18 | 21.8 |

For premedication the veterinary medicinal product should be administered at a dosage of 10-40 µg medetomidine hydrochloride per kg body weight, corresponding to 0.1-0.4 ml of the veterinary medicinal product per 10 kg body weight. The exact dose depends on the combination of drugs used and the dosage(s) of the other drug(s). The dose should furthermore be adjusted to the type of surgery, length of procedure and patient temperament and weight. Premedication with medetomidine will significantly reduce the dosage of the induction agent required and will reduce volatile anaesthetic requirements for maintenance anaesthesia. All anaesthetic agents used for induction or maintenance of anaesthesia should be administered to effect. Before using any combinations, product literature for the other veterinary medicinal products should be observed. See also the "special warnings" section.

Cats:
For moderate-deep sedation and restraint of cats the veterinary medicinal product should be administered at a dosage of 50 – 150 µg medetomidine hydrochloride /kg bw (corresp. to 0.05 – 0.15 ml of the veterinary medicinal product / kg bw). For anaesthesia the veterinary medicinal product should be administered at a dosage of 80 µg medetomidine hydrochloride / kg bw (corresp. to 0.08 ml of the veterinary medicinal product / kg bw) and 2.5 to 7.5 mg ketamine / kg bw. Using this dosage anaesthesia occurs within 3 – 4 minutes and is apparent for 20 – 50 minutes. For longer lasting procedures administration has to be repeated by using ½ of the initial dose (i.e. 40 µg medetomidine hydrochloride (corresp. to 0.04 ml of the veterinary medicinal product / kg bw) and 2.5 - 3.75 mg ketamine / kg bw) or 3.0 mg ketamine / kg bw alone. Alternatively, for longer lasting procedures anaesthesia may be extended by use of the inhalation agents isoflurane or halothane, with oxygen or oxygen/nitrous oxide. See also the "special warnings" section.

## 9. Advice on correct administration

## 10. Withdrawal periods

Not applicable.

## 11. Special storage precautions

Keep out of the sight and reach of children.

Do not freeze.

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

Shelf life after first opening the immediate packaging: 28 days.

## 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

Cardboard box with 1 clear glass type I vial of 5, 10 or 20 ml, with a teflon coated halogenated type I rubber stopper and aluminium cap.

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 and contact details to report suspected adverse reactions:
[Company logo]

Manufacturer responsible for batch release:
Eurovet Animal Health B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Local representatives and contact details to report suspected adverse reactions:

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

## 17. Other information