

## **ANNEX I**

### **SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cepetor KH 1 mg/ml Solution for Injection for Dog and Cat (DE)

Medetor 1 mg/ml Solution for Injection for Dog and Cat (AT, BE, ES, FR, IE, IT, PT, UK(NI))

Cepetor 1 mg/ml Solution for Injection for Dog and Cat (CZ, HU, LT, LV, NL, PL, SK)

Cepetor vet 1 mg/ml Solution for Injection for Dog and Cat (DK, FI, NO, SE)

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Medetomidine hydrochloride 1.0 mg  
(equivalent to 0.85 mg medetomidine)

### 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 (E 218)	1.0 mg
Propyl parahydroxybenzoate	0.2 mg
Sodium chloride	
Hydrochloric acid (for pH-adjustment)	
Sodium hydroxide (for pH-adjustment)	
Water for injections	

Clear colourless solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Dog and cat.

### 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).
- Pregnancy, 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 other excipients.

Do not use in animals with ocular problems where an increase in intraocular pressure would be detrimental.

### **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 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 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. As ketamine alone can elicit cramps, alpha-2 antagonists should be administered not before 30 - 40 min. after ketamine.

Medetomidine may cause respiratory depression and under these circumstances, manual ventilation and oxygen may be administered.

#### 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. 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 the case of accidental contact of the veterinary medicinal product with eyes, 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

Dog and cat:

Common (1 animal to 10 animals / 100 animals treated):	Vomiting <sup>1</sup>
Rare (1 to 10 animals / 10,000 animals treated):	Pulmonary oedema
Undetermined frequency (cannot be estimated from the available data)	<p>Increased sensitivity to sound</p> <p>Hyperglycaemia<sup>2</sup></p> <p>Bradycardia, Heart block 1st degree, Heart block 2nd degree, Extrasystole<sup>3</sup>, Vasoconstriction<sup>4</sup>, High blood pressure<sup>5</sup> Decreased cardiac output<sup>6,7</sup></p> <p>Respiratory depression<sup>7</sup></p> <p>Increased urine volume</p> <p>Hypothermia</p> <p>Mydriasis</p> <p>Cyanosis</p> <p>Injection site pain</p> <p>Muscle tremor</p>

<sup>1</sup> Some dogs and most cats will vomit within 5-10 minutes of injection. Cats may also vomit on recovery.

<sup>2</sup> Reversible, due to depression of insulin secretion

<sup>3</sup> Occasionally

<sup>4</sup> Of coronary artery

<sup>5</sup> Blood pressure will increase initially after administration and then return to normal, or slightly below normal.

<sup>6</sup> Atropine may increase the cardiac rate.

<sup>7</sup> Manual ventilation and an oxygen supplement may be indicated.

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 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 and lactation. Therefore, it should not be used 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 3.3

### 3.9 Administration routes and dosage

*Dogs:* Intramuscular or intravenous use.

*Cats:* Intramuscular use.

#### ***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.

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

body weight [kg]	i.v.- Injection		i.m.- Injection	
	[ml]	corresp. to [µg/kg bw]	[ml]	corresp. 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

<b>40</b>	<b>0.89</b>	22.2	<b>1.18</b>	29.5
<b>50</b>	<b>1.03</b>	20.6	<b>1.37</b>	27.4
<b>60</b>	<b>1.16</b>	19.3	<b>1.55</b>	25.8
<b>70</b>	<b>1.29</b>	18.4	<b>1.72</b>	24.6
<b>80</b>	<b>1.41</b>	17.6	<b>1.88</b>	23.5
<b>90</b>	<b>1.52</b>	16.9	<b>2.03</b>	22.6
<b>100</b>	<b>1.63</b>	16.3	<b>2.18</b>	21.8

#### For premedication:

10 - 40 µg medetomidine hydrochloride per kg body weight, corresponding to 0.1 - 0.4 ml 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 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 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 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). 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. Alpha-2 antagonists should be administered not before 30 - 40 min. after ketamine.

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 to 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 incompatibility 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**

This veterinary medicinal product does not require any special storage conditions.

### **5.4 Nature and composition of immediate packaging**

Glass (type I) vials closed with bromobutyl rubber closures secured with aluminium crimp caps.

Box of 1 glass vial with 10 ml.  
Box of 5 glass vials with 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**

CP-Pharma Handelsgesellschaft mbH

**7. MARKETING AUTHORISATION NUMBER(S)**

**8. DATE OF FIRST AUTHORISATION**

Date of first authorisation: DD/MM/YYYY

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

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 \(https://medicines.health.europa.eu/veterinary\)](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**

Cepetor KH 1 mg/ml Solution for Injection

**2. STATEMENT OF ACTIVE SUBSTANCES**

1 ml contains: Medetomidine hydrochloride 1 mg

**3. PACKAGE SIZE**

1 x 10 ml

5 x 10 ml

**4. TARGET SPECIES**

Dog and cat

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Dogs: **i.m.** or **i.v.**

Cats: **i.m.**

**7. WITHDRAWAL PERIODS**

**8. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 28 days – by.....

**9. SPECIAL STORAGE PRECAUTIONS**

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

<b>11. THE WORDS “FOR ANIMAL TREATMENT ONLY”</b>
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For animal treatment only.

<b>12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”</b>
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Keep out of the sight and reach of children.

<b>13. NAME OF THE MARKETING AUTHORISATION HOLDER</b>
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CP-Pharma Handelsges. mbH

<b>14. MARKETING AUTHORISATION NUMBERS</b>
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<b>15. BATCH NUMBER</b>
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Lot {number}

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

10 ml vial

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Cepetor KH

**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Medetomidine hydrochloride                      1.0 mg / ml

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {mm/yyyy}

Once opened use within 28 days – by.....

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Cepetor KH 1 mg/ml Solution for Injection for Dog and Cat

### 2. Composition

Each ml contains:

**Active substance:**

Medetomidine hydrochloride 1.0 mg  
(equivalent to 0.85 mg/ml medetomidine)

**Excipients:**

Methyl parahydroxybenzoate 1.0 mg  
Propyl parahydroxybenzoate 0.2 mg

Clear colourless solution.

### 3. Target species

Dog and cat.

### 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 (torsio ventriculi, incarcerations, oesophageal obstructions).
- Pregnancy, 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 other 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 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 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. As ketamine alone can elicit cramps, alpha-2 antagonists should be administered not before 30 - 40 min. after ketamine.

Medetomidine may cause respiratory depression and under these circumstances, manual ventilation and oxygen may be administered.

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. 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 the case of accidental contact of the veterinary medicinal product with eyes, 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 alpha<sub>2</sub>-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. Therefore, it should not be used 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 section “Special warnings”.

The effects of medetomidine may be antagonized by administration of atipamezole or yohimbine.

See also section “Contraindications”.

#### 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). 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. Alpha-2 antagonists should be administered not before 30 - 40 min. after ketamine.

If it is imperative to reverse bradycardia but maintain sedation, atropine may be used.

#### Major incompatibilities:

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

## **7. Adverse events**

Dog and cat:

Common (1 animal to 10 animals / 100 animals treated):	Vomiting <sup>1</sup>
Rare (1 to 10 animals / 10,000 animals treated):	Pulmonary oedema (fluid in lungs)
Undetermined frequency (cannot be estimated from the available data)	Increased sensitivity to sound Hyperglycaemia (high blood sugar) <sup>2</sup> Bradycardia (slow heart rate), Heart block 1st degree, Heart block 2nd degree, Extrasystole <sup>3</sup> , Vasoconstriction <sup>4</sup> , High blood pressure <sup>5</sup> , Decreased cardiac output <sup>6,7</sup> Respiratory depression <sup>7</sup> Increased urine volume Hypothermia (low body temperature) Mydriasis (dilated pupils)

	Cyanosis Injection site pain Muscle tremor
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<sup>1</sup> Some dogs and most cats will vomit within 5-10 minutes of injection. Cats may also vomit on recovery.

<sup>2</sup> Reversible, due to depression of insulin secretion

<sup>3</sup> Occasionally<sup>4</sup> Of coronary artery

<sup>5</sup> Blood pressure will increase initially after administration and then return to normal, or slightly below normal.

<sup>6</sup> Atropine may increase the cardiac rate.

<sup>7</sup> Manual ventilation and an oxygen supplement may be indicated.

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.

### ***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.

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

body weight [kg]	i.v.- Injection	corresp. to [µg/kg bw]	i.m.- Injection	corresp. to [µg/kg bw]
	[ml]		[ml]	
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

<b>12</b>	<b>0.40</b>	33.3	<b>0.53</b>	44.2
<b>14</b>	<b>0.44</b>	31.4	<b>0.59</b>	42.1
<b>16</b>	<b>0.48</b>	30.0	<b>0.64</b>	40.0
<b>18</b>	<b>0.52</b>	28.9	<b>0.69</b>	38.3
<b>20</b>	<b>0.56</b>	28.0	<b>0.74</b>	37.0
<b>25</b>	<b>0.65</b>	26.0	<b>0.86</b>	34.4
<b>30</b>	<b>0.73</b>	24.3	<b>0.98</b>	32.7
<b>35</b>	<b>0.81</b>	23.1	<b>1.08</b>	30.9
<b>40</b>	<b>0.89</b>	22.2	<b>1.18</b>	29.5
<b>50</b>	<b>1.03</b>	20.6	<b>1.37</b>	27.4
<b>60</b>	<b>1.16</b>	19.3	<b>1.55</b>	25.8
<b>70</b>	<b>1.29</b>	18.4	<b>1.72</b>	24.6
<b>80</b>	<b>1.41</b>	17.6	<b>1.88</b>	23.5
<b>90</b>	<b>1.52</b>	16.9	<b>2.03</b>	22.6
<b>100</b>	<b>1.63</b>	16.3	<b>2.18</b>	21.8

For premedication:

10 - 40 µg medetomidine hydrochloride per kg body weight, corresponding to 0.1 - 0.4 ml 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 "Special warning(s)".

**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 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 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 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 "Special warning(s)".

**9. Advice on correct administration**

**10. Withdrawal periods**

Not applicable.

**11. Special storage precautions**

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions

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

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

## **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**

Glass (type I) vials closed with bromobutyl rubber closures secured with aluminium crimp caps.

Box of 1 glass vial with 10 ml.

Box of 5 glass vials with 10 ml. Not all pack sizes may be marketed.

## **15. Date on which the package leaflet was last revised**

MM/YYYY

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

## **16. Contact details**

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

CP-Pharma Handelsgesellschaft mbH  
Ostlandring 13  
DE-31303 Burgdorf  
Tel: +49 (0) 5136-60660

Local representative and contact details to report suspected adverse reactions: