Labelling & Package Leaflet

Label of the outer carton

NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Medetomidine hydrochloride

STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml solution for injection contains:

Active substance:

Medetomidine hydrochloride	1.0 mg
(equivalent to 0.85 mg medetomidine)	

Excipients:

Methyl parahydroxybenzoate	1.0 mg
Propyl parahydroxybenzoate	0.2 mg

PHARMACEUTICAL FORM

Solution for injection.

PACKAGE SIZE

1 vial with 10 ml solution for injection.

5 vials with 10 ml solution for injection each.

TARGET SPECIES

Dog and cat.

INDICATION(S)

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.

METHOD AND ROUTE(S) OF ADMINISTRATION

The product is intended for:

Dogs: Intramuscular or intravenous injection.

Cats: Intramuscular injection.

WITHDRAWAL PERIOD

Not applicable.

SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

EXPIRY DATE

EXP:

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Batch:

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused product or waste materials should be disposed of in accordance with local requirements.

For animal treatment only.

To be supplied only on veterinary prescription.

Keep out of the reach and sight of children.

Do not freeze.

NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsges. mbH

Ostlandring 13, 31303 Burgdorf, Germany

MARKETING AUTHORISATION NUMBER

Label of the vial

NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Medetomidine hydrochloride

QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml solution for injection contains:

Active substance:

Medetomidine hydrochloride	1.0 mg
(equivalent to 0.85 mg medetomidine)	

Excipients:

Methyl parahydroxybenzoate	1.0 mg
Propyl parahydroxybenzoate	0.2 mg

CONTENTS BY VOLUME

1 vial with 10 ml solution for injection.

ROUTE(S) OF ADMINISTRATION

Dogs: Intramuscular or intravenous injection.

Cats: Intramuscular injection.

WITHDRAWAL PERIOD

Not applicable

Batch:

EXP:

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Once opened, use by ...

For animal treatment only.

Keep out of the reach and sight of children.

Package leaflet

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

CP-Pharma Handelsges. mbH
Ostlandring 13
31303 Burgdorf, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

Medetomidine hydrochloride

DE: Cepetor KH 1 mg/ml Solution for Injection for Dog and Cat
AT: Medetor 1 mg/ml Solution for Injection for Dog and Cat
BE: Medetor 1 mg/ml Solution for Injection for Dog and Cat
ES: Medetor 1 mg/ml Solution for Injection for Dog and Cat
FR: Medetor 1 mg/ml Solution for Injection for Dog and Cat
IE: Medetor 1 mg/ml Solution for Injection for Dog and Cat
IT: Medetor 1 mg/ml Solution for Injection for Dog and Cat
PL: Medetor 1 mg/ml Solution for Injection for Dog and Cat
PT: Medetor 1 mg/ml Solution for Injection for Dog and Cat
UK: Medetor 1 mg/ml Solution for Injection for Dog and Cat
DK: Cepetor vet 1 mg/ml Solution for Injection for Dog and Cat
FI: Cepetor vet 1 mg/ml Solution for Injection for Dog and Cat
NO: Cepetor vet 1 mg/ml Solution for Injection for Dog and Cat
SE: Cepetor vet 1 mg/ml Solution for Injection for Dog and Cat

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

Cepetor is a clear colourless, sterile aqueous solution for injection containing:

Active substance:

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

Excipients:

Methyl parahydroxybenzoate	1.0 mg/ml
Propyl parahydroxybenzoate	0.2 mg/ml

4. INDICATION(S)

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, oesophagal obstructions).
- Pregnancy, Diabetes mellitus.
- State of shock, emaciation or serious debilitation.

Do not use concomitantly with sympathomimetic amines.

Do not use in cases of known 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. ADVERSE REACTIONS

Bradycardia with atrioventricular block (1th and 2nd degree) and occasionally extrasystolia.

Vasoconstriction of coronary artery. Decreased cardiac output. Blood pressure will increase initially after administration and then return to normal, or slightly below normal. Some dogs and most cats will vomit within 5-10 minutes of injection. Cats may also vomit on recovery. Sensitivity to loud noises is observed in some individuals.

Increased diuresis. Hypothermia. Mydriasis. In rare cases pulmonary oedema has been observed. Respiratory depression, cyanosis, pain at injection site and muscle tremor may be seen. In individual cases reversible hyperglycaemia due to depression of insulin secretion.

In circulatory and respiratory depression manual ventilation and an oxygen supplement may be indicated. Atropine may increase the cardiac rate.

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

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dog and cat.

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

Cepetor is intended for:

Dogs: Intramuscular or intravenous injection.

Cats: Intramuscular injection.

Dogs:

For sedation the 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.

Cepetor dosages in ml and corresponding amount of medetomidine hydrochloride in µg /kg bw):

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

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 products should be observed. See also section 4.5.

Cats:

For moderate-deep sedation and restraint of cats the product should be administered at a dosage of 50 – 150 µg medetomidine hydrochloride / kg bw (corresp. to 0.05 – 0.15 ml **Cepetor** / kg bw).

For anaesthesia the product should be administered at a dosage of 80 µg medetomidine hydrochloride / kg bw (corresp. to 0.08 ml **Cepetor** / 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 **Cepetor** / 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 section 12.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not freeze.

Do not use after the expiry date stated on the label and on the carton.

Shelf-life after first opening the container: 28 days

12. SPECIAL WARNING(S)

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 use in animals

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 the case of accidental oral intake or self-injection, seek medical advice immediately and show the package insert 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 product with eyes, rinse abundantly with fresh water. If symptoms occur, seek the advice of a physician.

If pregnant women handle the product, special caution should be observed not to self-inject as uterine contractions and decreased foetal blood pressure may occur after accidental systemic exposure.

Advice to doctors:
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.

Use during pregnancy, lactation or lay

The safety of the 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 5.
The effects of medetomidine may be antagonized by administration of atipamezole or yohimbine.

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

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 **Cepetor**, 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

1 x 1 glass vial with 10 ml.
5 x 1 glass vials with 10 ml.

Not all pack sizes may be marketed.