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## CEPETOR™

(Medetomidine hydrochloride injection - 1mg/mL)

DIN 02337177

Injectable sedative and analgesic for use in dogs only  
Sterile Solution  
For veterinary use only.

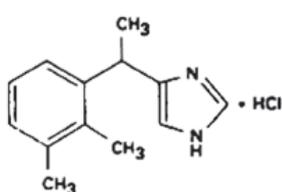
**Active ingredient - Each mL contains:**

Medetomidine hydrochloride..... 1 mg

**Non-medicinal ingredients - Each mL contains:**

Methylparahydroxybenzoate (preservative) ..... 1 mg  
Propylparahydroxybenzoate (preservative) ..... 0.2 mg  
Sodium chloride.....9 mg  
Water for injection..... q.s.

**Description:** CEPETOR™ (medetomidine hydrochloride) is a synthetic  $\alpha_2$ -adrenoreceptor agonist with sedative and analgesic properties. The chemical name is  $(\pm)$ -4-[1-(2,3-dimethylphenyl) ethyl]-1H-imidazole monohydrochloride. It is a white, or almost white, crystalline, water soluble substance having a molecular weight of 236.7. The molecular formula is  $C_{13}H_{16}N_2 \cdot HCl$  and the structural formula is:



**Clinical pharmacology:** CEPETOR™, a non-narcotic sedative and analgesic, is a potent  $\alpha_2$ -adrenoreceptor agonist which produces sedation and analgesia. These effects are dose dependent in depth and duration. Profound sedation and recumbency, with reduced sensitivity to environmental stimuli (sounds, etc.), are seen with medetomidine. The pharmacological restraint and pain relief provided by medetomidine facilitates handling dogs and aids in the conduct of diagnostic or therapeutic procedures. It also facilitates minor surgical procedures (with or without local anesthesia) and dental care where intubation is not required. Spontaneous muscle contractions (twitching) can be expected in some dogs sedated with medetomidine. With medetomidine administration, blood pressure is initially increased due to peripheral vasoconstriction and thereafter drops to normal or slightly below normal levels. The initial vasopressor response is accompanied by a compensatory marked decrease in heart rate mediated by a vagal baroreceptor mechanism. The bradycardia may be partially prevented by prior (at least 5 minutes before) intravenous administration of an anticholinergic agent (see Caution). A transient change in the conductivity of the cardiac muscle may occur, as evidenced by atrioventricular blocks. Cardiovascular changes (such as profound bradycardia and second degree heart block) equally affect both heartworm negative and asymptomatic heartworm positive dogs. Respiratory responses include an initial slowing of respiration within a few seconds to 1-2 minutes after administration, increasing to normal within 120 minutes. An initial decrease in tidal volume is followed by an increase. When medetomidine was given at 3 and 5 times the recommended dose IV, and 5 and 10 times IM, effects were not intensified but were prolonged.

**Indications:** CEPETOR™ is indicated for use as a sedative and analgesic to facilitate clinical examinations, clinical procedures, minor surgical procedures with the exception of those requiring muscle relaxation and minor dental procedures where intubation is not required, in dogs over 12 weeks of age. The IV route of administration is more efficacious for dental care.

**Dosage and Administration:** CEPETOR™ should be administered at the rate of 750  $\mu$ g IV or 1000  $\mu$ g IM per square meter of body surface. Use the table below to determine the correct dosage on the basis of body weight.

Body weight (kg) IV Administration	Injection Volume (mL)	Body weight (kg) IM Administration
1.5 - 2.2	0.1	1.8 - 2.3
2.3 - 3.5	0.15	2.4 - 3.3
3.6 - 5.1	0.2	3.4 - 4.5
5.2 - 6.9	0.25	4.6 - 6.4
7.0 - 9.9	0.3	6.5 - 9.4
10.0 - 14.4	0.4	9.5 - 12.7
14.5 - 19.5	0.5	12.8 - 16.3
19.6 - 25.1	0.6	16.4 - 20.2
25.2 - 31.1	0.7	20.3 - 24.4
31.2 - 37.6	0.8	24.5 - 28.9
37.7 - 44.4	0.9	29.0 - 36.1
44.5 - 55.3	1.0	36.2 - 46.3
55.4 - 71.1	1.2	46.4 - 57.3
71.2 - 88.2	1.4	57.4 - 75.8
88.3+	1.5	75.9+
	2	

Following injection, the animal should be allowed to rest quietly for 15 minutes.

**Contraindications:** CEPETOR™ should not be used in dogs with the following conditions: cardiac disease, respiratory disorders, liver or kidney disease, dogs in shock, dogs which are severely debilitated, or dogs which are stressed due to extreme heat, cold or fatigue.

**Caution:** In extremely nervous or excited dogs, levels of endogenous catecholamines are high due to the animal's state of agitation. The pharmacological response elicited by  $\alpha_2$ -agonists (e.g., medetomidine) in such animal is often reduced, with depth and duration of sedative/analgesic effects ranging from slightly diminished to nonexistent. Highly agitated dogs should therefore be put at ease and allowed to rest quietly prior to receiving CEPETOR™. In dogs not responding satisfactorily to treatment with CEPETOR™, repeated dosing is not recommended.

CEPETOR™ is a potent  $\alpha_2$ -agonist which should be used with caution with other sedative or analgesic drugs. Additive or synergistic effects are likely, possibly resulting in overdose. The administration of anticholinergic agents to treat bradycardia either simultaneously with medetomidine or following sedation with medetomidine could lead to adverse cardiovascular effects. Do not use concomitantly with sympathomimetic amines.

The intramuscular administration of atipamezole hydrochloride, an  $\alpha_2$ -adrenergic agonist, is indicated for the reversal of the clinical effects of the sedative and analgesic agent, medetomidine hydrochloride, in dogs. Special care is recommended when treating very young animals, debilitated older animals, coughing dogs, or dogs with poor general condition. Information on the possible reproductive effects of medetomidine is limited; therefore, the drug is not recommended for use in dogs used for breeding purposes or in pregnant dogs.

**NOTE TO USERS:** Care should be taken to assure that CEPETOR™ is not inadvertently ingested as safety studies have indicated that the drug is absorbed when administered orally. As with all injectable drugs causing profound physiological effects, routine precautions should be employed when handling and using filled syringes, including washing eye and skin areas affected by accidental spillage. In case of accidental human exposure, a physician should be contacted. For intramuscular and intravenous use in dogs only.

**Warning:** Keep out of reach of children. Not for human use.

**Safety studies:** Medetomidine is tolerated in dogs at up to 5 and 10 times the recommended IV and IM dosages, respectively. A single IV administration of 10 times the recommended dose in dogs caused a prolonged anesthesia-like condition accompanied by an increased level of spontaneous twitching. Repeated IV doses of 3 or 5 times the recommended dose caused a profound sedation, bradycardia, and reduced respiratory rates over several hours, accompanied in some animals by occasional twitching.

**Adverse Reactions:** As with all  $\alpha_2$ -agonists, the potential for isolated cases of hypersensitivity, including paradoxical response (excitation), exists. Incidents of prolonged sedation, bradycardia, cyanosis, vomiting, and reoccurrence of sedation after initial recovery have been reported (See Caution for reversal of clinical effects).

Bradycardia with occasional atrioventricular blocks will occur together with decreased respiratory rates. Body temperature is slightly or moderately decreased. Urination typically occurs during recovery at about 90-120 minutes post treatment. In approximately 10% of treated dogs, occasional episodes of vomiting occur between 5-15 minutes post treatment. An increase in blood glucose concentration is seen due to  $\alpha_2$ -adrenoreceptor mediated inhibition of insulin secretion.

**Post-approval experience:** Although all adverse reactions are not reported, the following adverse reaction information is based on voluntary post-approval drug experience reporting. It is generally recognized that this method of reporting results in a significant under-reporting of adverse drug reactions. It should also be noted that suspected adverse drug reactions listed here reflect reporting and not causality. The categories of adverse reactions are listed in decreasing order of frequency by body system:  
Neurological: CNS depression, seizures  
In few instances, death has been reported.

**Storage:** Store at controlled room temperature 15-30°C. Protect from freezing.

**Presentation:** CEPETOR™ is supplied in 10-mL multi-dose vials containing 1.0 mg of medetomidine hydrochloride per mL.

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