



Quality you can trust!





<u>Sedator</u>

Sedator, a 1,0 mg/ml medetomidine hydrochloride solution for injection, has been registered for dogs and cats. Sedator, a chemically and physically stable product, can be used for intravenous, and intramuscular administration in dogs and intramuscular administration in cats. Sedator is a potent and specific α_2 adrenergic agonist, that provides sedation and analgesia.

Use

Sedator is used in practise for its good sedative and analgesic properties.

- **Dogs:** For sedation Sedator 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. For premedication Sedator should be administered at a dosage of 10-40 µg medetomidine hydrochloride per kg body weight, corresponding to 0.1-0.4 ml Sedator per 10 kg body weight.
- Cats: For moderate-deep sedation and restraint of cats, Sedator should be administered at a dosage of 50 150 μg medetomidine hydrochloride /kg bw (corresp. to 0.05 0.15 ml Sedator / kg bw). For anaesthesia Sedator should be administered at a dosage of 80 μg medetomidine hydrochloride/kg bw (corresp. to 0.08 ml Sedator / kg bw) and 2.5 to 7.5 mg ketamine / kg bw.

Indications

In dogs and cats:

- Sedation to facilitate handling.
- Premedication prior to general anaesthesia.

In cats the combination Sedator and ketamine is often used for general anaesthesia for minor surgical procedures of short duration.

Advantages of Sedator

- Potent agent for sedation and premedication prior to general anaesthesia
- Available in 5 ml, 10 ml and 20 ml (country dependent)
- Antagonisation very easy with atipamezole
- Very well suited in combination with agents like ketamine, butorphanol, propofol, thiopentone, and alphaxalone/alphadolone, depending on species and country. Read insert for details.
- Effective and safe

Comparitive study Sedator - original

Two 2-sided-cross-over double blinded GLP studies were performed, in order to show that Sedator and the original product are equally effective and equally safe. One study was performed in dogs and one in cats. Both products (test- (Sedator) and reference product) contained 1,0 mg/ml medetomidine.¹

Study design

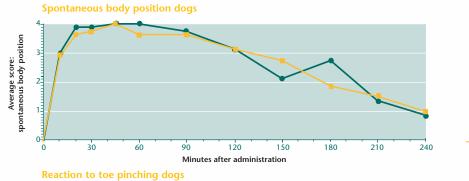
- Eight healthy dogs and eight healthy cats were given both products with a wash out period of one week. Per species first four animals were given the test product and the other four animals the reference product. One week later this was turned around.
- The products were administered intramuscularly to the dogs in a dosage of 0.05 mg medetomidine hydrochloride per kg bodyweight and to the cats in a dosage of 0.1 mg per kg bodyweight.
- In order to evaluate efficacy and safety certain parameters were scored.

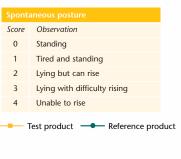
Parameters

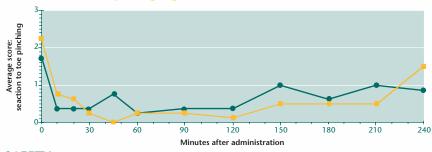
Efficacy	Safety
Spontaneous body position	Heart rate
Reaction to toe pinching	Respiratory rate

Results in dogs

EFFECTIVENESS

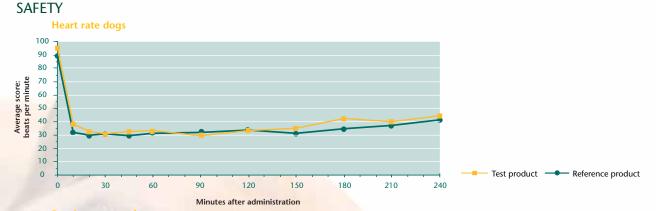


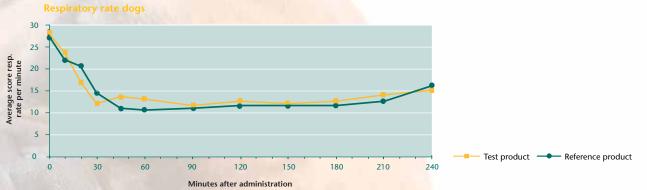




ScoreObservation0No response1Moderate damping	
1 Moderate damping	
2 Slightly damping	
3 Normal	

Test product
Reference product

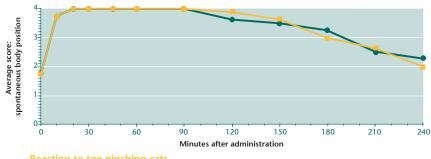




Results in cats

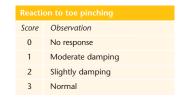
EFFECTIVENESS



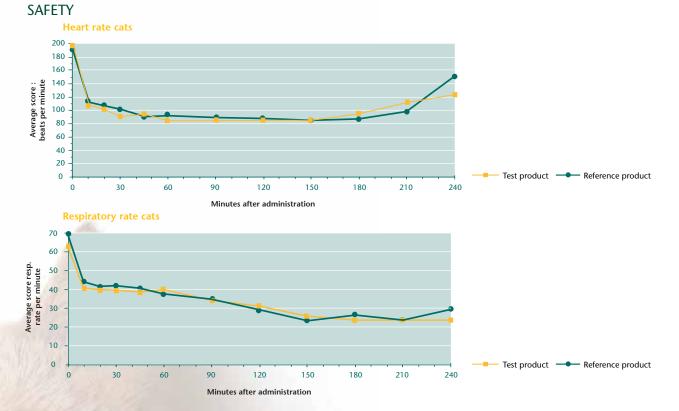












Conclusions

As both products are solutions that are administered parentally and contain the same ingredients in the same concentrations, they can be considered bio-equivalent per definition.

Based on the scored data and the comparable time effect curves the generic formulation and the original can be considered equally effective and equally safe.¹

Possibilities to combine with other anaesthetics

Literature describes many possibilities to combine medetomidine with other agents. By combining sedatives and anaesthetics from different groups, dosages can be lower compared to single use. This results in less side effects and easier recovery.

Sedator can be combined with many other agents.

Reference

¹ Boezeman et al., Twee medetomidine formuleringen voor hond en kat. Dier en Arts, 2007

Product Information

Please add here the product information or insert, as required by your authorities.

Product Information (continued)

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