

# Loud noises can be scary.

**SILEO<sup>®</sup> (dexmedetomidine oromucosal gel) is the first and only FDA-approved medication indicated for the treatment of noise aversion in dogs.**



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**IMPORTANT SAFETY INFORMATION SILEO:** Do not use SILEO in dogs with severe cardiovascular disease, respiratory, liver or kidney diseases, or in conditions of shock, severe debilitation, or stress due to extreme heat, cold or fatigue or in dogs hypersensitive to dexmedetomidine or to any of the excipients. SILEO should not be administered in the presence of preexisting

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# Noises scary.

(dexmedetomidine oromucosal gel) is the  
most loved medication indicated  
to reduce noise aversion in dogs.

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## Canine Noise Aversion

Noise aversion is an anxiety and fear-based reaction to noise commonly referred to as noise reactivity, anxiety or phobia.

### Canine noise aversion facts:

- At least one-third of all dogs in the United States have noise aversion,<sup>1</sup> which leads to distress and suffering.<sup>2,3</sup>
- Noise aversion progresses to a more severe state if ineffectively treated.
- Common clinical signs include panting, trembling, cowering, and escape behavior, which can result in self-trauma as well as property damage.<sup>4</sup>
- Pet owners and veterinarians report that fireworks and thunderstorms are the top triggers for noise aversion in dogs.<sup>4</sup> In fact, July 5th is the busiest day for shelter intakes in the United States.<sup>5</sup>
- 69% of pet owners are “neutral” to “dissatisfied” with current treatment options, with unmet need for consistent results without sedation or behavior modification.<sup>4</sup>

**Fireworks**      **Thunder**      **Celebrations**

**Triggers** ↗

**Clingy 59%**      **Hiding**      **Panting 45%**

**Clinical Signs** ↗

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## Canine Noise Aversion: Triggers



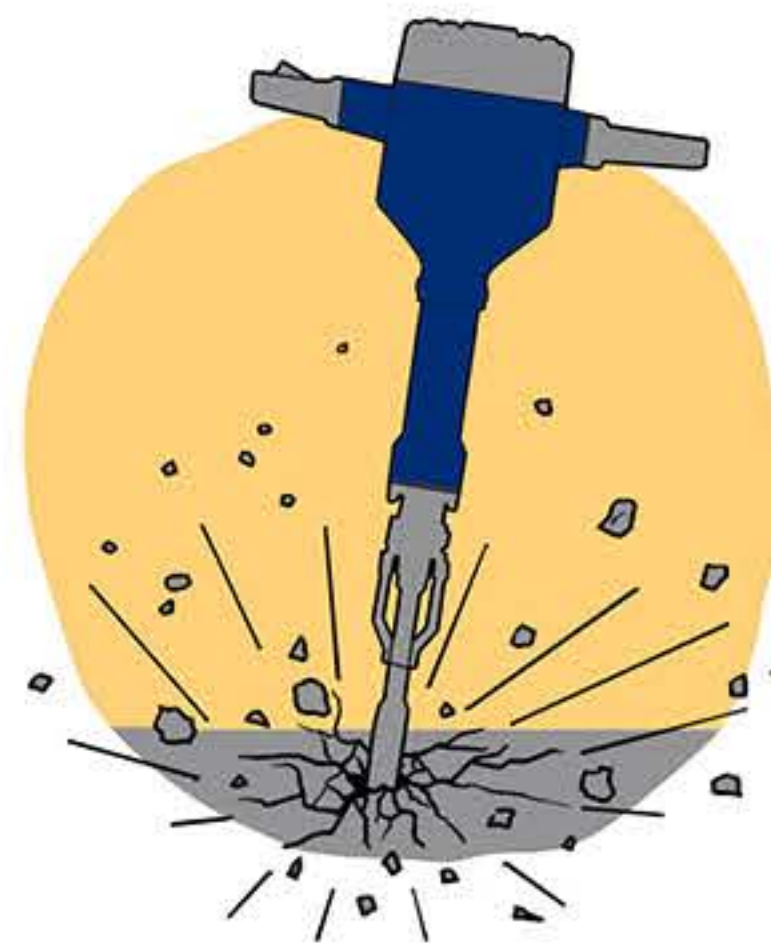
Fireworks



Thunder



Celebrations



Construction Work



Traffic or Street Noise

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Celebrations



Panting  
45%

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## Canine Noise Aversion: Common Behaviors

Frequency of behaviors reported by pet owners<sup>4</sup>



**Trembling/shaking/  
ears back**  
**63%**



**Clingy**  
**59%**



**Hiding**  
**56%**



**Panting**  
**45%**



**Pacing/restless**  
**44%**



**Whining/whimpering/  
barking**  
**44%**



**Cowering**  
**37%**



**Hypervigilant**  
**30%**



**Tries to escape/  
does escape**  
**17%**



**Lip licking and/  
or yawning**  
**15%**



**Chews/destroys  
furniture, walls, etc.**  
**5%**

## Canine

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Celebrations



Panting  
45%

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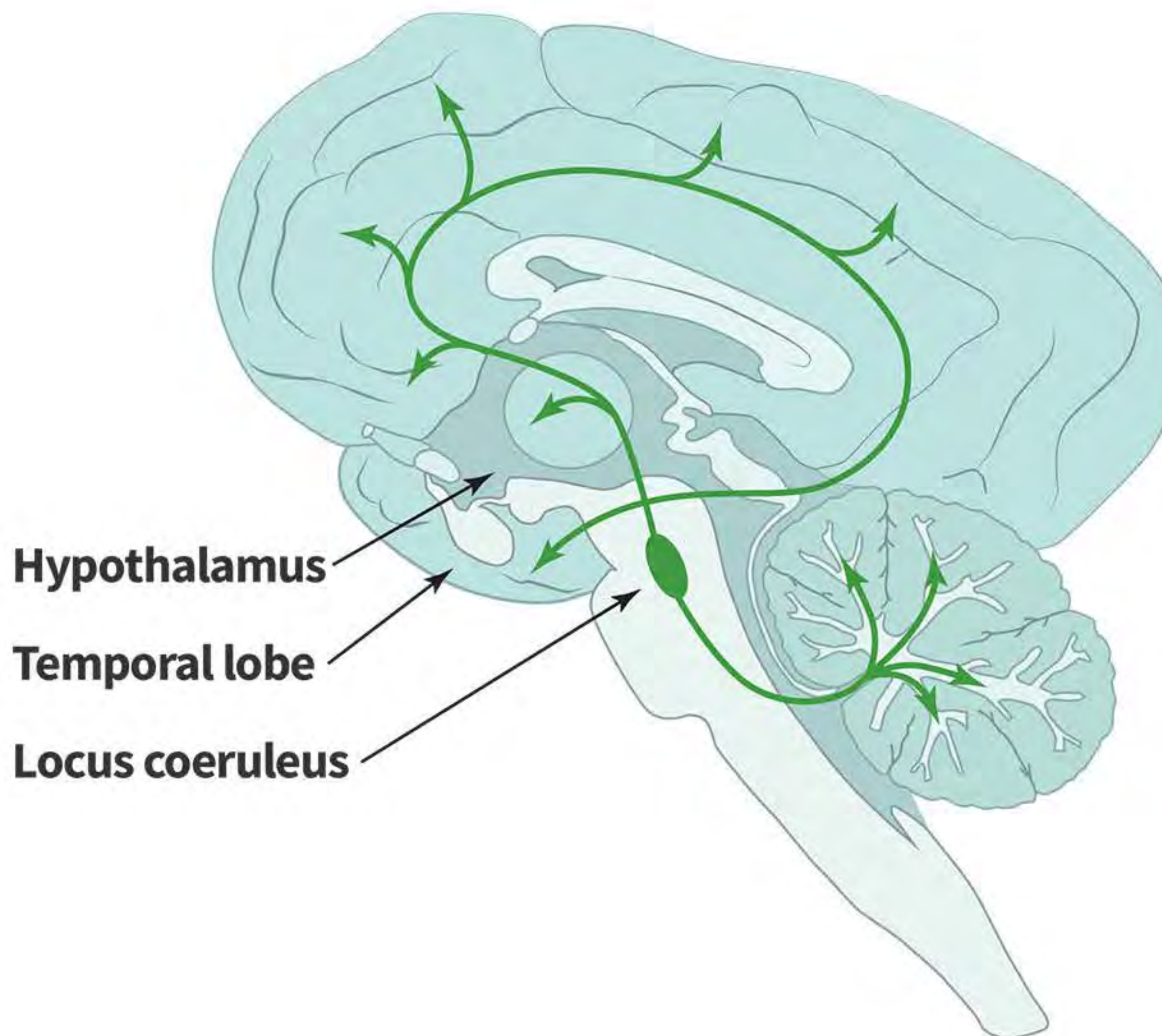


## Neurobiology of Noise Aversion

**Noise aversion is caused by an uncontrolled fear of noise, similar to an “anxiety attack.”**

- Noise aversion is thought to originate in the locus coeruleus
- Locus coeruleus is the area of the brain that moderates stress and anxiety, fear and fear learning
- There is a high concentration of alpha-2 adrenoceptors in the locus coeruleus
- The main neurotransmitter is norepinephrine
- Norepinephrine levels in the locus coeruleus increase during anxiety

Therefore, it makes sense to use a medication that inhibits norepinephrine release to treat noise aversion.



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## Introducing SILEO<sup>®</sup> (dexmedetomidine oromucosal gel)

### The first and only FDA-approved treatment for noise aversion.

SILEO is an oromucosal gel formulation of dexmedetomidine that blocks the release of norepinephrine. SILEO is provided in a 3 mL syringe.



### Practical for Your Clients

- Calming without sedating,\* allowing for normal dog-owner interactions
- Administer at home when needed
- Easy-to-use syringe
- Works on its own without any other treatments or training

### Relief for Your Patients

- Quick onset of action
- Supports early intervention for optimal effect on the quality of life of the dog<sup>6</sup>

### Confidence for You and Your Team

- Proven to be safe and effective in a randomized, placebo-controlled clinical trial
- An easy treatment for a challenging condition
- [Comprehensive pet owner education resources](#) »

\*The calming effects of SILEO are not due to sedation. However, dogs that are sensitive to SILEO or that receive a higher than label dose may become sedated.

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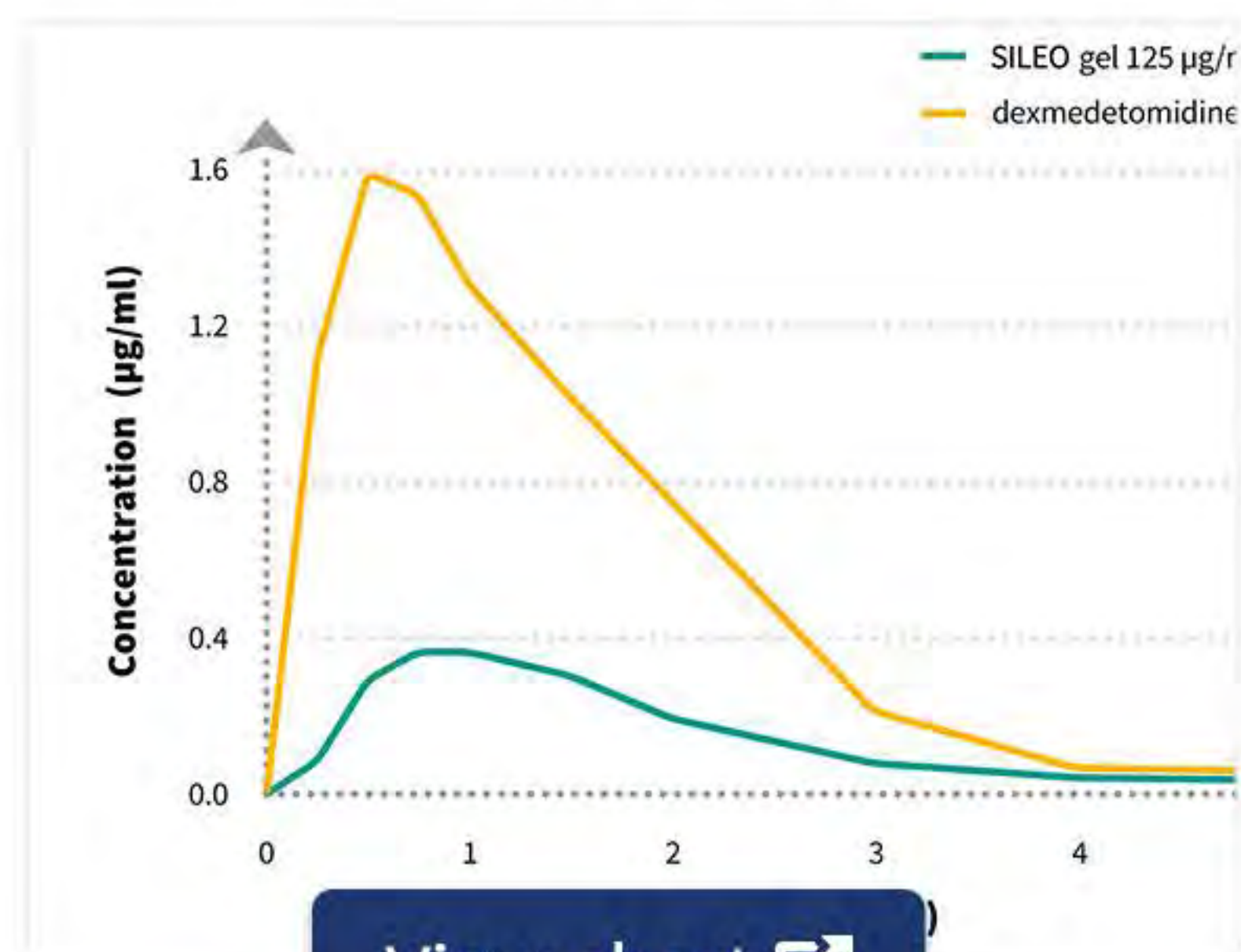


# Pharmacology of SILEO<sup>®</sup> (dexmedetomidine oromucosal gel)

The dosage of SILEO is 125mcg/m<sup>2</sup>: this is the same as the preanesthetic dosage of DEXDOMITOR<sup>®</sup> (dexmedetomidine). Although the dosage is the same, the effects are different. Pharmacology explains “Why?”.

## Bioavailability

Bioavailability of oral transmucosally (OTM) administered dexmedetomidine is 28%



[View chart](#)

## Sedation

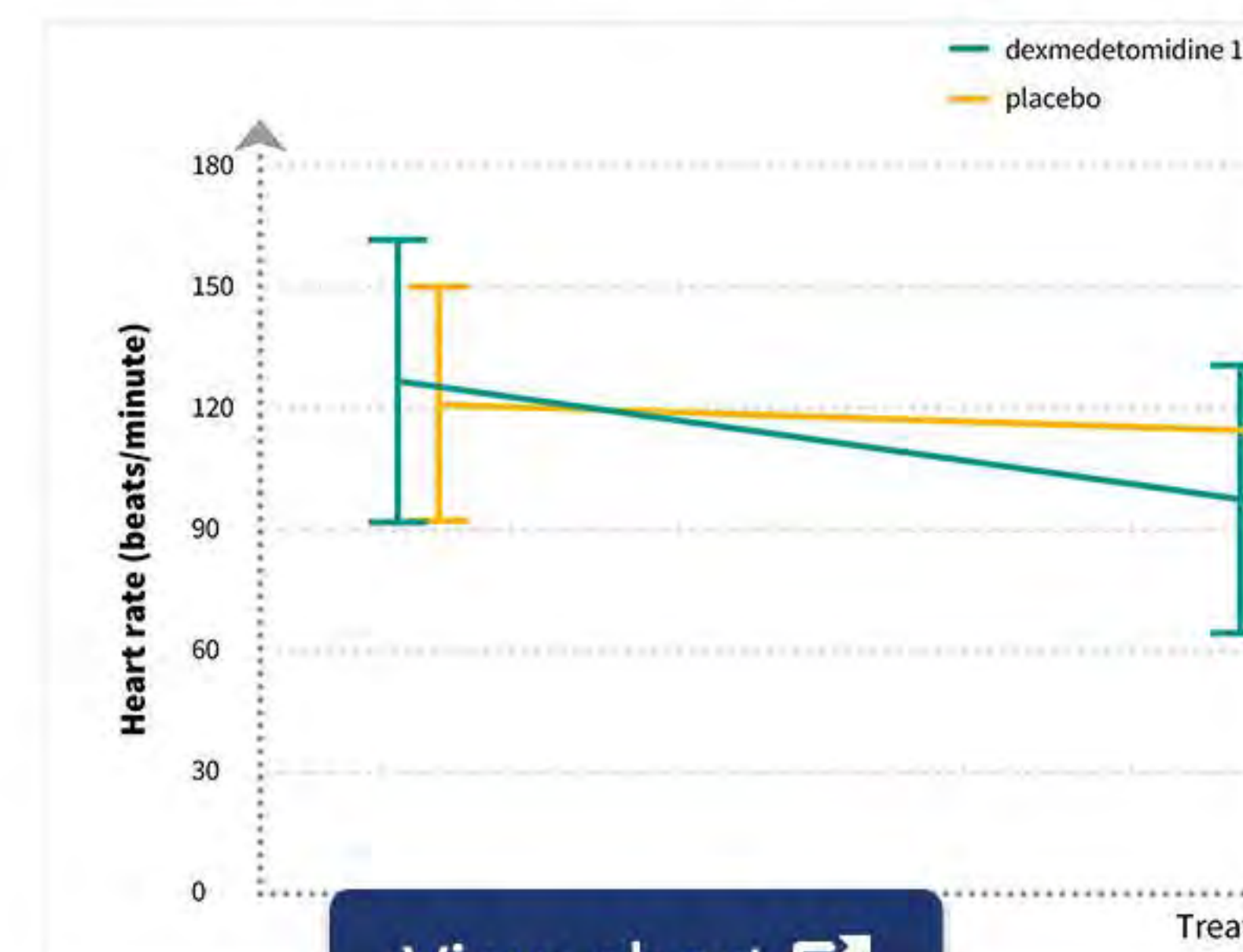
Lower dexmedetomidine plasma concentration results in minimal sedation.



[View chart](#)

## Heart Rate

Lower dexmedetomidine plasma concentration results in minimal impact on heart rate.



[View chart](#)

[SHOW](#)

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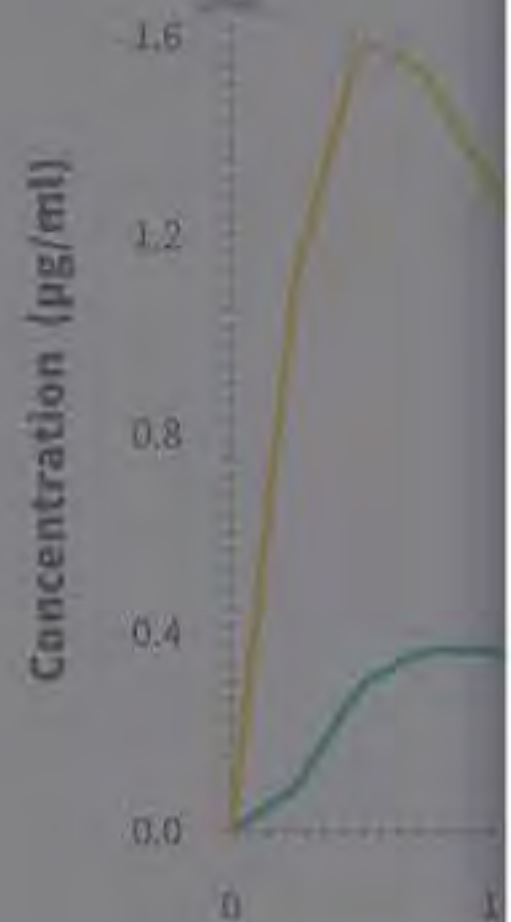


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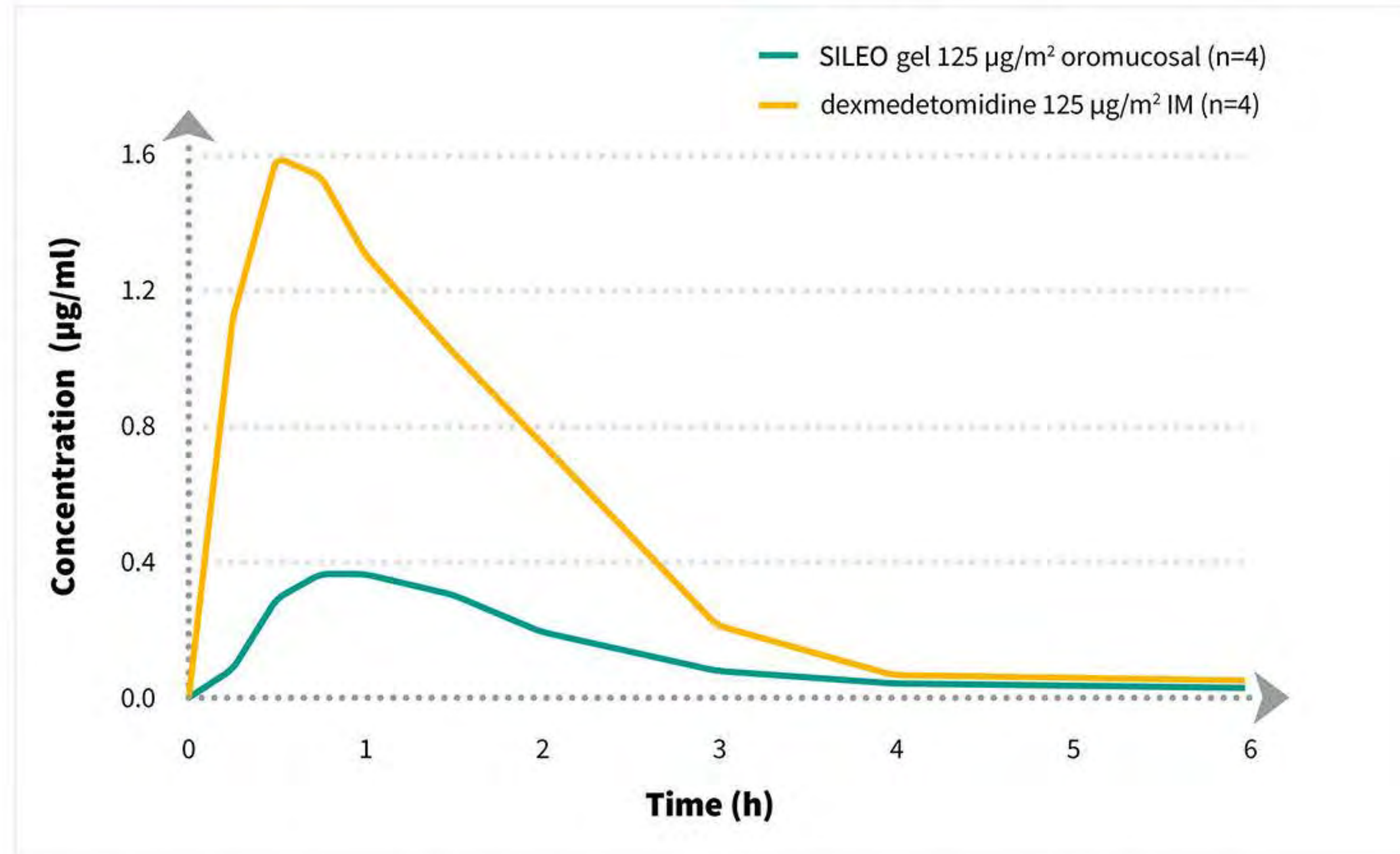
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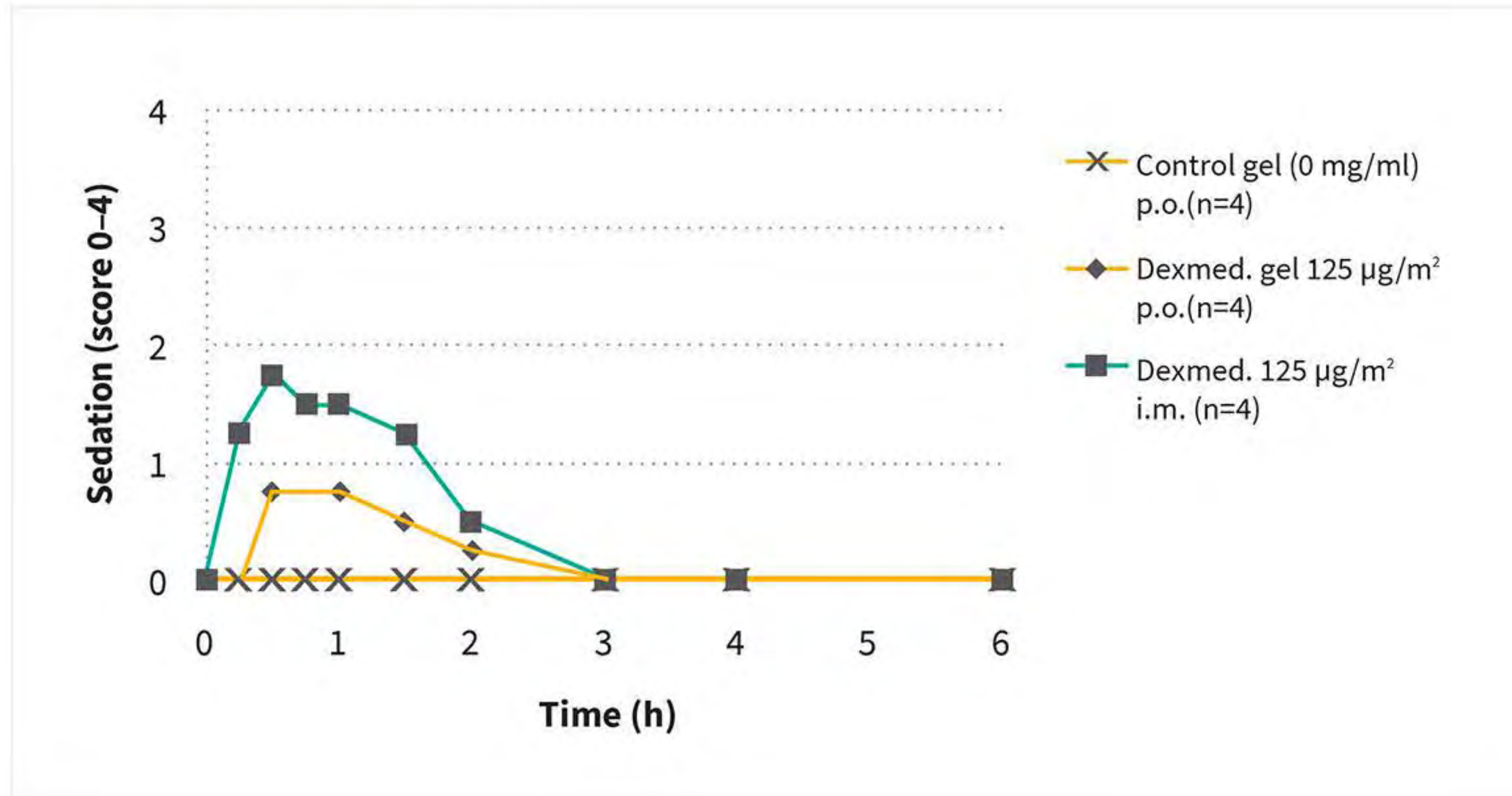


**Bioavailability**



Comparison of the mean dexmedetomidine blood concentrations after oromucosal (125 µg/m², SILEO gel) and intramuscular (125 µg/m², dexmedetomidine solution for injection) administration in dog plasma (n=4).

## Mean Sedation Scores



### Sedation score:

**0**=normal

**1**=slightly tired, the eyelids hanging (mild sedation)

**2**=tired but standing, hangs the head (moderate sedation)

**3**=unable to stand, responds to a touch by the evaluator (moderate sedation)

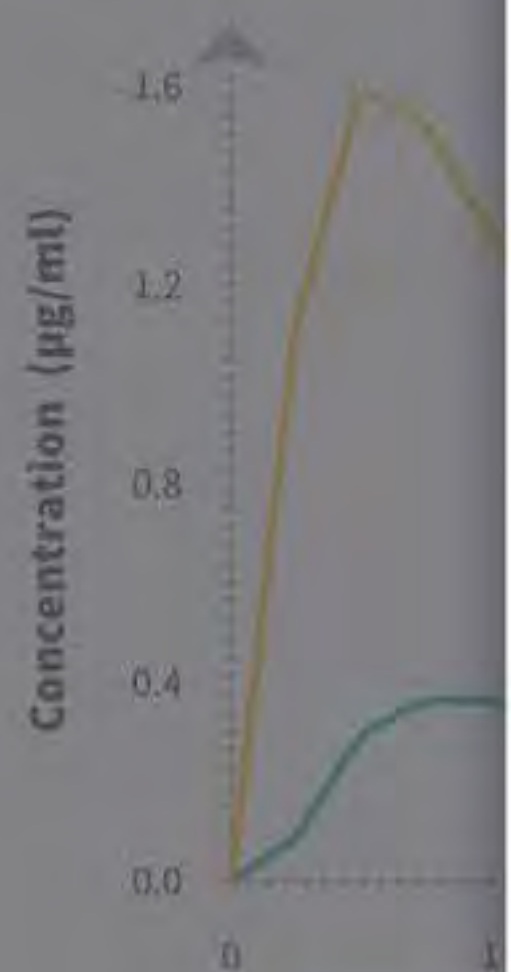
**4**=unable to stand, does not respond to a pinch by the evaluator (deep sedation)

# Pharm

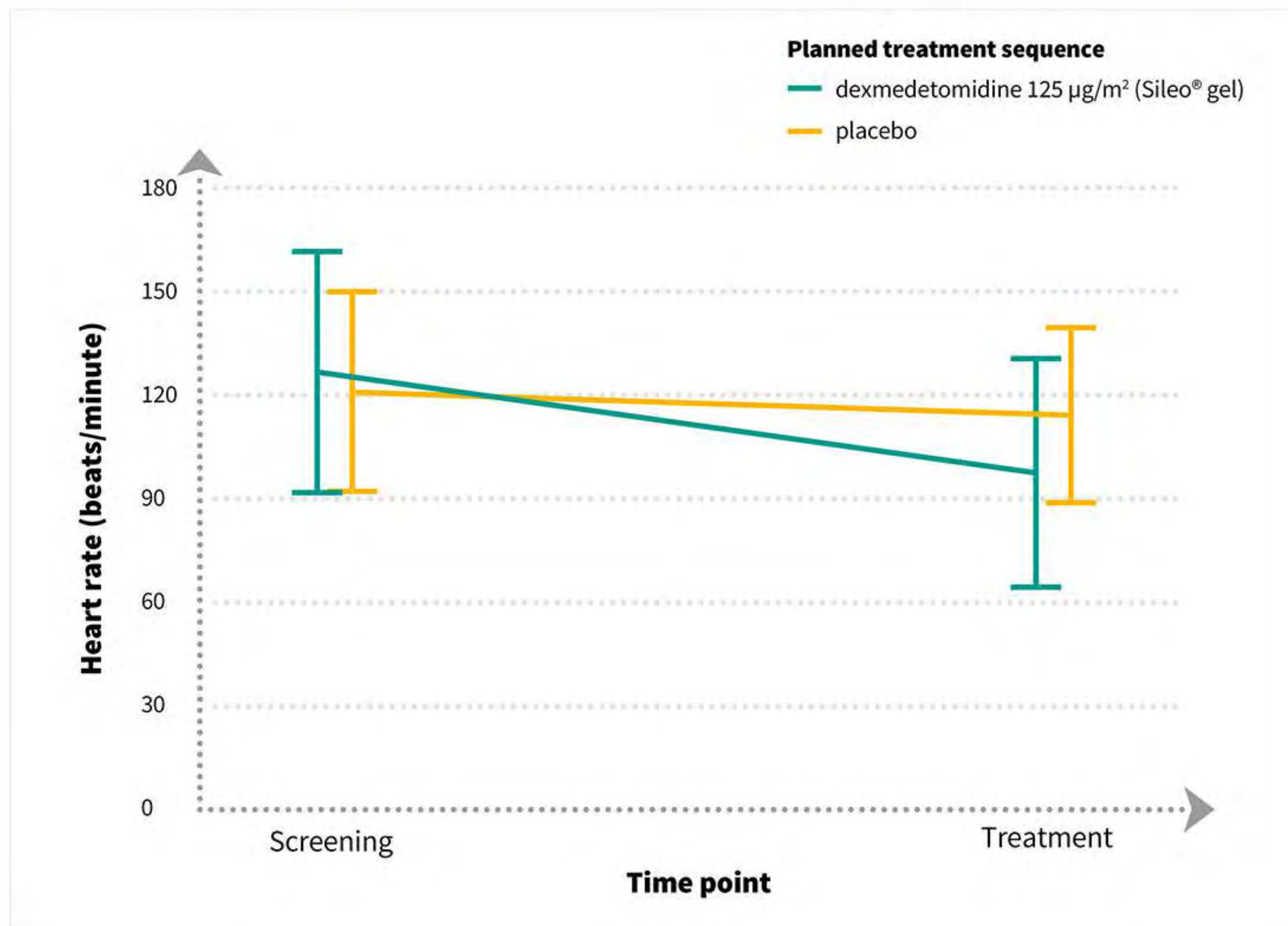
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Bioavailability of  
administered dex



## Mean Heart Rate



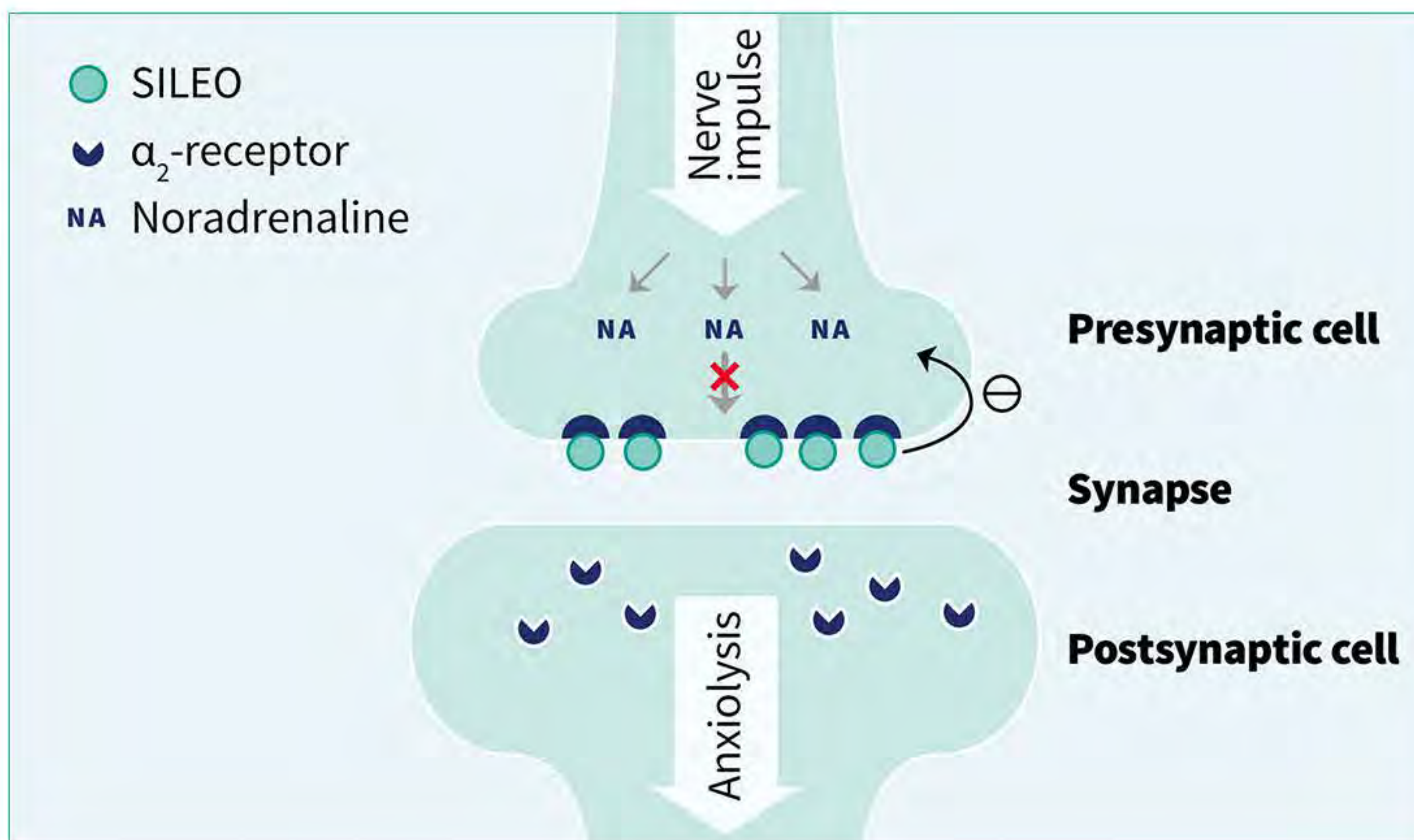
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## Mechanism of Action<sup>7,8</sup>

The anxiolytic effect of SILEO<sup>®</sup> (dexmedetomidine oromucosal gel) is mediated through the locus coeruleus. Dexmedetomidine, the active substance of SILEO, is a highly potent and selective alpha-2 adrenoceptor agonist.

- Dexmedetomidine binds with the alpha-2 adrenoceptors in the locus coeruleus, preventing release of norepinephrine
- Reduced levels of norepinephrine reduce the levels of anxiety and fear



[Mechanism of Action Video](#)

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# Sileo<sup>®</sup> (dexmedetomidine) Mechanism of Action

Sileo<sup>®</sup>  
(dexmedetomidine  
oromucosal gel)

zoetis



0:01



-3:47





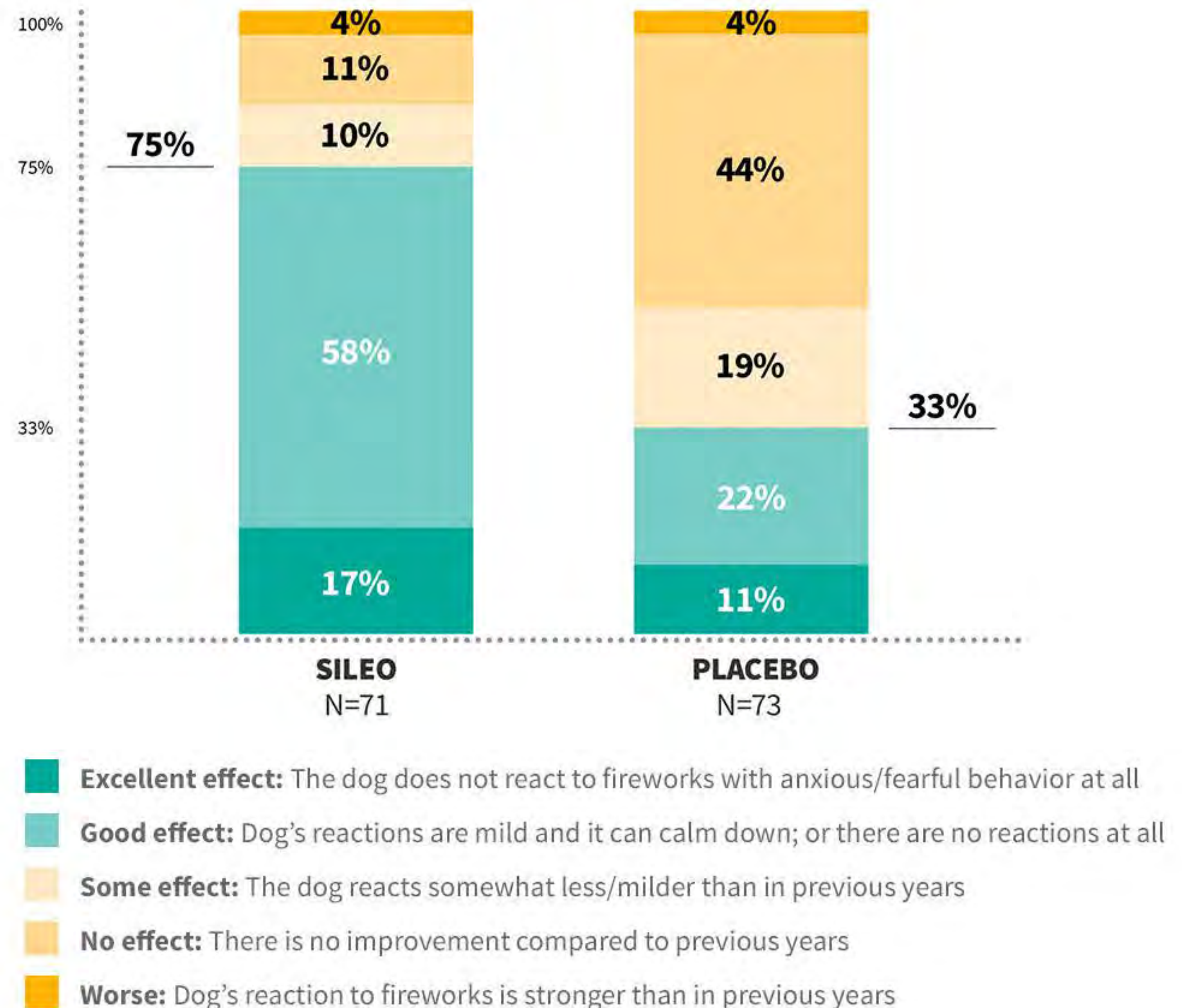
## Efficacy of SILEO<sup>®</sup> (dexmedetomidine oromucosal gel)

Efficacy was evaluated in two studies conducted on New Year's Eve in Europe\* to explore treatment effect under the actual conditions of use with an authentic noise stimulus: fireworks.

Study treatment effect was measurable and statistically significant ( $p < 0.0001$ ), in favor of SILEO.

SILEO had a “good” or “excellent” effect in 75% of dogs in the randomized, blinded, placebo-controlled pivotal field study.

\*Finland and Germany were selected because New Year's Eve fireworks last throughout the night.



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## Safety of SILEO<sup>®</sup> (dexmedetomidine oromucosal gel)

Adverse effects were few and mild.

### Adverse Reactions – Number (%) of dogs

Adverse Reactions	Control N=92	SILEO 125 mcg/m <sup>2</sup> N=89
Emesis	1 (1.1)	4 (4.5)
Gastroenteritis	0	1 (1.1)
Periorbital Edema	0	1 (1.1)
Drowsiness	0	1 (1.1)
Sedation	0	1 (1.1)

A dose reduction was required for one dog receiving SILEO due to sedation/drowsiness.

Transient pale mucous membranes were reported more frequently in SILEO treated dogs.

**Conclusion:** Administration of 125 µg/m<sup>2</sup> of SILEO as needed up to 5 times (minimum interval 2 hours between doses) is safe and effective.

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## When to Administer SILEO<sup>®</sup> (dexmedetomidine oromucosal gel)

### SILEO administration can be tailored to the situation.

Dose is selected based on body weight, which correlates with a specific number of dots. Each dot is equivalent to 0.25 mL of SILEO.

#### The first dose can be administered:

- Approximately 30 to 60 minutes before the fear and/or anxiety eliciting noise stimulus
- Or immediately after the dog shows first signs of anxiety or fear related to noise
- Or when the owner detects a typical noise stimulus (e.g., fireworks) eliciting anxiety or fear in the dog

#### If the noise lasts more than 2–3 hours and the dog’s signs of fear and/or anxiety reappear, another dose may be given:

- At minimum intervals of 2 hours between doses
- Up to five doses can be given during one noise event



### Dosing Chart

Bodyweight of dog (lb)	Dose/Number of dots	Full doses in 1 syringe
<b>4.4–12.1</b>	1 ●	12
<b>12.2–26.5</b>	2 ●●	6
<b>26.6–44.0</b>	3 ●●●	4
<b>44.1–63.9</b>	4 ●●●●	3
<b>64.0–86.0</b>	5 ●●●●●	2
<b>86.1–110.2</b>	6 ●●●●●●	2
<b>110.3–137.8</b>	7 ●●●●●●●	1
<b>137.9–166.4</b>	8 ●●●●●●●●	1
<b>166.5–196.2</b>	9 ●●●●●●●●●	1
<b>196.3–220.5</b>	10 ●●●●●●●●●●	1

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## How to Administer SILEO<sup>®</sup> (dexmedetomidine oromucosal gel)

### SILEO is easy to administer.

- In a usability study in which pet owners were instructed on how to use the syringe correctly, **92%** of pet owners assessed using the the syringe to be "easy" or "very easy."

**As with any new medication, it is important that the dog owner receives hands-on training on how to administer the treatment. Review the dosing administration instructions to:**

**Confirm the correct dose and emphasize to the pet owner that the syringe is locked and that SILEO is administered oral transmucosally.**

- SILEO is administered between the cheek and gums for oromucosal absorption.
- SILEO may be ineffective if swallowed.
- If there is any SILEO remaining in the syringe, the syringe should be returned to the carton to protect it from light.
- If the remaining portion of SILEO in the syringe is not used within 2 weeks, it should be discarded according to local and federal regulations.

### How to Administer SILEO Correctly



### Further Dosing



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## Clinic Resources

Select file(s) below to share by email:

- |   |  |
|---|--|
| <input checked="" type="checkbox"/> How to Administer SILEO Correctly (Video) | <input checked="" type="checkbox"/> Prescribing Information (PDF)                |
| <input type="checkbox"/> Further Dosing (Video)                               | <input type="checkbox"/> Client Communication Tools (Zip)                        |
| <input type="checkbox"/> 13 Common Signs of Noise Aversion in Dogs (Video)    | <input type="checkbox"/> SILEO One-pager (PDF)                                   |
| <input type="checkbox"/> Dosing Chart (PDF)                                   | <input type="checkbox"/> Veterinarian Brochure (PDF)                             |
| <input type="checkbox"/> Instructions for Dosing (PDF)                        | <input type="checkbox"/> Poster: Does your dog suffer from noise aversion? (PDF) |
|   | <input type="checkbox"/> Veterinarian FAQs (PDF)                                 |

Email Selected Resources

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Cancel

New Message

To: |



Cc/Bcc: johndoe@zoetisrep.com

Subject: Thanks for meeting with me! Here are your SILEO resources.

Hi-

Thanks for the chance to talk with you about SILEO® (dexmedetomidine oromucosal gel).  
I appreciate your time.

You cover a lot during patient exams, and noise aversion might not be top of mind. In a survey, 88% of veterinarians said their clients initiate discussions about their dog's noise aversion.<sup>1</sup>

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Hi—

Thanks for the chance to talk with you about SILEO® (dexmedetomidine oromucosal gel). I appreciate your time.

You cover a lot during patient exams, and noise aversion might not be top of mind. In a survey, 88% of veterinarians said their clients initiate discussions about their dog's noise aversion.<sup>1</sup>

Now that there is an FDA-approved treatment for noise aversion, these conversations can be easier. Use these tools to open and support a dialogue with clients about their dog's noise aversion.

Here are the SILEO materials you requested during our discussion. Click a file name to download the document:

- [How to Administer SILEO Correctly \(Video\)](#)
- [Dosing Further Dose \(Video\)](#)
- [13 Common Signs of Noise Aversion in Dogs \(Video\)](#)
- [Dosing Chart \(PDF\)](#)
- [Instructions for Dosing \(PDF\)](#)
- [Prescribing Information \(PDF\)](#)
- [Client Brochure \(PDF\)](#)
- [Social Media Posts \(Zip\)](#)
- [Email Templates \(Zip\)](#)
- [Poster: Does your dog suffer from noise aversion? \(PDF\)](#)
- [Veterinarian FAQs](#)

If you have any questions about these materials or about SILEO, feel free to get in touch with me. Again, thanks for your time and your interest in SILEO.

Regards,  
Zoetis Representative

#### References

1. FR Market Research – Noise Aversion; February 2016; N=472 Dog Owners, N=454 General Practitioners.

Zoetis  
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Parsippany, New Jersey 07054

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# Loud noises

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**DEXDOMITOR AND DEXDOMITOR 0.1:** Do not use DEXDOMITOR or DEXDOMITOR 0.1 in dogs or cats, and ANTISEDAN in dogs, with cardiovascular disease, respiratory disorders, liver or kidney diseases, or in conditions of shock, severe debilitation, or stress due to extreme heat, cold or fatigue. DEXDOMITOR and DEXDOMITOR 0.1 should not be administered in the presence of preexisting hypotension, hypoxia, or bradycardia. As with all  $\alpha_2$ -adrenoceptor agonists, the potential for isolated cases of hypersensitivity, including paradoxical response (excitation), exists with DEXDOMITOR and DEXDOMITOR 0.1. The use of DEXDOMITOR and DEXDOMITOR 0.1 as a preanesthetic in dogs and cats significantly reduces the amount of induction and maintenance anesthetic requirements. Careful patient monitoring is necessary to avoid anesthetic overdose. Arrhythmias, bradycardia, apnea, emesis, convulsions, hypersalivation may occur with DEXDOMITOR and DEXDOMITOR 0.1 use. Severe dyspnea and respiratory crackles due to acute or delayed pulmonary edema could develop in cats. DEXDOMITOR and DEXDOMITOR 0.1 have not been evaluated for use in breeding, pregnant, or lactating dogs or cats; in dogs younger than 16 weeks of age or in cats younger than 12 weeks of age; or in geriatric dogs or cats. Occasional vomiting may occur with ANTISEDAN use. Rarely, a brief state of excitement or apprehensiveness may be seen in ANTISEDAN-treated dogs. Other potential side effects of  $\alpha_2$ -antagonists, such as ANTISEDAN, include hypersalivation, diarrhea, and tremors. See full [Prescribing Information](#).



## References

1. Based on online survey conducted by Harris Poll on behalf of Zoetis in November 2013 among 784 dog owners.
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