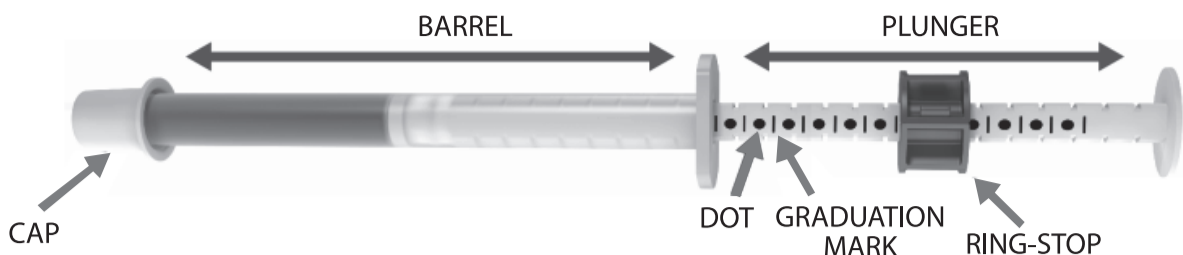


**KEEP THIS CLIENT INFORMATION SHEET IN THE CARTON WITH THE SILEO DOSING SYRINGE
REVIEW PRIOR TO GIVING EACH DOSE TO YOUR DOG**

**SILEO (dexmedetomidine oromucosal gel)
CLIENT INFORMATION SHEET FOR OWNER/HANDLER USE AND SAFETY**

This sheet summarizes the basic information about SILEO and does not replace the instructions from your veterinarian. Talk to your veterinarian if you have questions regarding any part of this information or if you want to know more about SILEO. The syringe must be used in order to correctly dose the drug to your dog. You may use either a full, unused syringe or a partially used syringe that contains enough gel for the desired dose.



INSTRUCTIONS FOR USE

A. NEW SYRINGE SET UP BEFORE FIRST DOSING:

	<p>1. Wear impermeable disposable gloves when handling SILEO and handling the oral syringe.</p>
	<p>2. Hold the oral syringe so that you can see the dot markings on the oral syringe plunger.</p>
	<p>3. Hold the plunger with your left hand and unlock the green ring-stop by turning it towards you until it is able to slide freely.</p>
	<p>4. Move the ring-stop to the opposite end of the plunger.</p>
	<p>5. Hold the plunger with your right hand and lock the ring-stop by turning it away from you. Confirm that the ring-stop is in the locked position on the dosing syringe by making sure it is not freely moveable.</p>

B. DOSE SELECTION AND DOSING:

	<p>6. Hold the plunger with your right hand and unlock the ring-stop by turning it towards you. Do not pull the plunger!</p>
	<p>7. Move the ring-stop towards the other end of the plunger for choosing the correct dose based on your veterinarian's prescription.</p>
	<p>8. Position the ring-stop so that the side nearest the barrel is in line with the graduation mark (black line), and the required number of dots shows between the ring-stop and the barrel. Lock the ring-stop by turning it away from you. Make sure that the ring-stop is in the locked position on the dosing syringe prior to administration in order to prevent accidental overdose.</p>
	<p>9. Pull the cap strongly while holding the barrel. Note the cap is very tight (pull, do not twist). Save the cap for replacement. Confirm the ring-stop is still in the locked position on the dosing syringe by making sure that it is not freely moveable.</p>
	<p>10. Place the oral syringe tip between your dog's cheek and gum and press the plunger until the ring-stop causes the plunger to stop. IMPORTANT: The gel should not be swallowed. If the gel is swallowed, it may not be effective.</p>
	<p>Feeding and giving treats within 15 minutes after administration should be avoided.</p>
	<p>11. Recap the oral syringe and return it to the outer package as the product is sensitive to light. Make sure that the carton is closed properly. Keep the package out of sight and reach of children at all times. Remove and discard gloves. Use or discard syringe contents within 4 weeks after opening the syringe.</p>

What is SILEO?

SILEO is a prescription product containing dexmedetomidine hydrochloride. It is used to treat noise aversion in dogs. Typical signs of anxiety and fear associated with noise aversion are panting, trembling, pacing, seeking people, trying to hide, trying to escape, freezing behavior, refusing to eat food or treats, inappropriate urination and/or defecation, and salivation. SILEO is packaged in a syringe that can be used to apply more than one dose. The medication should not be swallowed by your dog but should be placed in the dog's mouth between the cheek and gum, so that it can be absorbed into the bloodstream. If SILEO is swallowed, it may not be effective. If you think this has happened, you should wait for two hours and if your dog is showing signs of fear and/or anxiety, then administer another dose.

How should the product be handled?

You should wear impermeable disposable gloves when administering the product and when handling the dosing syringe. Avoid administering the product if pregnant, as exposure may induce uterine contractions and/or decrease fetal blood pressure.

When to administer and what should I expect after administering SILEO?

The first dose of SILEO should be given immediately after your dog shows first signs of fear and/or anxiety associated with noise, or when the typical noise stimulus (e.g. sound of fireworks) inducing anxiety and/or fear in your dog is detected. If the dose for your dog is more than 6 dots, divide the dose between both sides of the mouth. The drug takes effect after approximately 30 minutes to one hour. Your dog should show less intense noise aversion behavior, despite the ongoing noise. Some dogs might be more sensitive to the drug; if your dog appears drowsy, keep it warm and do not offer food or water until the effect of the drug has worn off. This will normally happen within a few hours.

What should I do if SILEO does not work?

If you think that SILEO is not working, do not re-dose and contact your veterinarian to discuss further treatment options.

If needed, is it possible to give another dose of SILEO?

If noise lasts longer than 2-3 hours and your dog is still showing signs of fear and/or anxiety or the signs of fear and anxiety reappear, you may need to give your dog another dose. To avoid overdosing, there should always be at least two hours' pause between dosages. Dogs sedated from previous dosing should not be given SILEO. No more than 5 doses can be given during one noise event. You can use a partially used syringe again within 4 weeks after initial opening, if there is enough gel for a complete dose for your dog. To minimize the risk of incorrect dosing, do not use a partially used syringe that does not have enough gel for a complete dose. Any unused product or waste material should be disposed of according to local law and Federal prescription drug disposal guidelines. Ask your veterinarian for this information.

What should I do if I have accidentally given my dog too much SILEO?

Contact your veterinarian immediately.

What if I get the gel in my eyes, nose, or mouth?

The drug can be absorbed into your body through your eyes, nose, or mouth. If it comes in contact with your eyes, nose, or mouth, flush with water for 15 minutes. If wearing contact lenses, eyes should be rinsed first, then remove contact lenses and continue rinsing, then seek medical advice immediately. If the drug is absorbed into your body, it can cause symptoms such as lowered blood pressure (which may result in dizziness; fainting; lack of concentration; blurred vision; nausea; cold, clammy, or pale skin; rapid, shallow breathing), sleepiness, and slower heart rate. Share the package information with your physician and tell the physician that the product contains an alpha-2 adrenoceptor agonist.

What if I get the gel on my skin?

You should wear impermeable disposable gloves when administering this product. If you have cuts or chapped skin, the drug can be absorbed into your body. In case of skin contact, wash immediately with large amounts of water. Remove contaminated clothing. Contact your physician if you have any questions or concerns. To report adverse reactions, call: 1-888-963-8471.

What else should I know about SILEO?

As with all prescription medicine, SILEO should only be given to the dog for which it was prescribed. This sheet provides a summary of information about SILEO. If you have any questions or concerns about SILEO or its effects on your dog, talk to your veterinarian or health care provider.

Which dogs should not take SILEO?

Dogs with severe cardiovascular, respiratory, liver or kidney disease or in dogs sedated from previous dosing should not be given SILEO.

What are the possible side effects that may occur in my dog after being given SILEO?

Possible side effects include vomiting, diarrhea, sedation, decreased heart rate, decreased respiratory rate and pale gums.

How do I store SILEO?

Store unopened and opened syringes at room temperature in the original package, as SILEO is sensitive to light. If syringe contents are not used within 4 weeks after opening the syringe, the syringe should be discarded. Keep the package out of sight and reach of children at all times.