Dexmedetomidine, Transmucosal
(deks-mee-deh-toe-mih-deen)

**Description:** Treatment of noise aversion in dogs

**Other Names for this Medication:** Sileo®

**Common Dosage Forms: Veterinary:** 0.09 mg/mL in 3-mL dosing syringes. Human: None.

This information sheet does not contain all available information for this medication. It is to help answer commonly asked questions and help you give the medication safely and effectively to your animal. If you have other questions or need more information about this medication, contact your veterinarian or pharmacist.

**Key Information**
- Labeled for use in dogs to treat fears and anxieties related to noises.
- Wear impermeable gloves when applying this medicine.
- Avoid handling this medicine if you are pregnant.
- Make sure the dosing ring is locked in place prior to administration to prevent accidental overdose.
- The medication should be administered between your dog's cheek and gums. This medicine is not intended to be swallowed.
- If your veterinarian has authorized giving a second dose of this medicine, wait at least 2 hours after the first dose. Additional doses should only be given if your dog is showing signs of fear or anxiety and is not sleepy from the previous dose.
- Dispose of empty containers in the regular trash.

**How is this medication useful?**
The FDA (U.S. Food & Drug Administration) has approved this medicine for use in dogs to treat fears and anxieties related to loud noises (i.e., noise aversion). The FDA allows veterinarians to prescribe and use products containing this drug in different species or for other conditions in certain situations. You and your veterinarian can discuss why this drug is the most appropriate choice.

**What should I tell my veterinarian to see if this medication can be safely given?**
Many things might affect how well this drug will work in your animal. Be sure to discuss the following with your veterinarian so together you can make the best treatment decisions.
- Other drugs can interact with this medication, so be sure to tell your veterinarian and pharmacist what medications (including vitamins, supplements, or herbal therapies) you give your animal, including the amount and time you give each.
- Tell your veterinarian about any conditions or diseases your animal may have now or has had in the past.

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If your animal has been treated for the same disease or condition in the past, tell your veterinarian about the treatment and how well it did or didn’t work.

If your animal is pregnant or nursing, talk to your veterinarian about the risks of using this drug.

Tell your veterinarian and pharmacist about any medication side effects (including allergic reactions, lack of appetite, diarrhea, itching, hair loss) your animal has developed in the past.

How long until I will know if this medication is working, and how long will the effects of this medication last?
This medication should help your animal feel better within 30 to 60 minutes. Your animal’s clinical signs should improve after that time. The effects of this medication are short-lived, meaning they will stop working within 24 hours, although the benefits may be prolonged if your animal has decreased kidney and/or liver function.

When should this medication not be used or be used very carefully?
No drug is 100% safe in all patients, but your veterinarian will discuss with you any specific concerns about using this drug in your animal.

This drug SHOULD NOT be used in:
- Cats
- Dogs that are allergic to dexmedetomidine
- Dogs with severe heart, lung, liver, or kidney problems
- Dogs that are severely debilitated
- Dogs that are stressed due to extreme heat or cold
- Dogs that are pregnant, used for breeding, or are lactating
- Dogs that are sedated from a previously given dose of this medicine

This drug should be used WITH CAUTION in:
- Dogs that are younger than 16 weeks of age (dogs)
- Old, weak, or debilitated animals
- Animals with dental or gingival problems
- That are taking other medications that may depress the nervous system

If your animal has any of these conditions, talk to your veterinarian about the potential risks versus benefits.

What are the side effects of this medication?

Side effects that usually are not serious include:
- Vomiting, diarrhea
- Drowsiness, sedation, low energy level
- Pale gums
- Slow heart rate and decreased breathing rate

If any of these signs are severe, worsen, or continue to be a problem, contact your veterinarian.

Side effects that may be serious or indicate a serious problem:
- Collapse
- Inability to wake your animal
- Persistent vomiting or diarrhea

If you see any of these signs, contact your veterinarian immediately.

If my animal gets too much of this medication (an overdose), what should I do?
If you witness or suspect an overdose, contact your veterinarian or an animal poison control center for further advice. Animal poison control centers open 24-hours a day include: Pet Poison HELPLINE (855-764-7661) and ASPCA Animal Poison Control Center (888-426-4435); a consultation fee may be charged for these services.

How should this medication be given?
For this medication to work properly, give it exactly as your veterinarian has prescribed. Check the prescription label and package insert to be sure you are giving the drug correctly.
Give the first dose 30-60 minutes before the noise stimulus is expected to occur.

- If your veterinarian has authorized repeating doses during a noise event, wait at least 2 hours between doses. Only repeat a dose if your dog is still fearful or anxious and is not sleepy from the previous dose. Do not give more than 5 doses during any one noise event.
- Feeding and giving treats within 15 minutes after administration should be avoided.

**FROM SILEO® CLIENT INFORMATION SHEET:**

*New syringe set-up before first dosing:*

1. Wear impermeable disposable gloves when handling SILEO and handling the oral syringe.
2. Hold the oral syringe so that you can see the dot markings on the oral syringe plunger.
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.
4. Move the ring-stop to the opposite end of the plunger.
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.

**Dose selection and dosing:**

1. Hold the plunger with your right hand and unlock the ring-stop by turning it towards you. Do not pull the plunger!
2. Move the ring-stop towards the other end of the plunger for choosing the correct dose based on your veterinarian’s prescription.
3. 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.
4. 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.
5. 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. If your dog’s prescription is for more than 6 dots, divide the dose between both sides of the mouth. IMPORTANT: The gel should not be swallowed. If the gel is swallowed, it may not be effective.
6. 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 out of reach of children at all times. Remove and discard gloves. Use or discard syringe contents within 4 weeks after opening the syringe.

- If you have difficulty getting your animal to take the medicine, contact your veterinarian or pharmacist for tips to help with dosing and reduce the stress of medication time for both you and your animal.
- This medication can be given for various lengths of time. Be sure you understand how long the veterinarian wants you to continue giving this medication. Prescription refills may be necessary before the therapy will be complete. If you want to stop giving this medication, talk to your veterinarian, as there may be important reasons to continue giving it.

**What should I do if I miss giving a dose of this medication?**

If you miss a dose, give it when you remember and then wait the amount of time between doses recommended by your veterinarian before the next dose. Do not double-up or give extra doses. Always wait at least 2 hours between doses.

**How should I store this medication?**

- Store this medication in the original prescription container at room temperature (68°F-77°F) and protected from light.
- After opening a syringe, the entire contents should be used within 4 weeks. Dispose unused portion.
- If your veterinarian or pharmacist has prepared (compounded) a special formulation for your animal, follow the storage recommendations and expiration date for the product.
- Keep away from children and other animals.

**Can handling this medication be hazardous to me, my family, or other animals?**

The SILEO® product label states:

- Avoid administering product if pregnant due to risk of adverse effects to the fetus.
- Impermeable disposable gloves should be worn when administering the medication and handling the syringe to prevent absorption through the skin.
**FIRST AID**

- **SKIN EXPOSURE:** If skin is damaged, dexmedetomidine can be absorbed into the body. In case of skin contact, wash with soap and water. Remove contaminated clothing.

- **EYE EXPOSURE:** In case of accidental eye exposure, 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.

- **ACCIDENTAL INGESTION:** Accidental ingestion may cause sedation and changes in blood pressure. In case of accidental exposure, seek medical attention immediately. Exposure to the product may induce a local or systemic allergic reaction in sensitized individuals.

- Contact your physician if you have any questions or concerns.

**How should I dispose of this medication if I don’t use it all?**

- Do not flush this medication down the toilet or wash it down the sink. If a community drug “take-back” program is available, use this option. If there is no take-back program, mix the drug with coffee grounds or cat litter (to make it undesirable to children and animals and unrecognizable to people who might go through your trash), place the mixture in a sealable plastic bag to keep it from leaking out and throw the bag out with the regular trash.

- Do not save leftover medication for future use or give it to others to use.

**What other information is important for this medication?**

- To minimize incorrect dosing, only administer medicine from partially used syringes if there is enough medicine remaining in the syringe for a complete dose.

- Keep your dog warm and do not offer food or water until the sedation effect has worn off.

- While your animal is under the effects of this medicine, keep your animal safe around open doorways and stairs and monitor your animal closely around water sources.

- Use of this drug may not be allowed in certain animal competitions. Check rules and regulations before entering your animal in a competition while this medication is being administered.

**If you have any other questions about this medication, contact your veterinarian or pharmacist.**