

Sileo[®] FAQs

Please find below some guidance related to Frequently Asked Questions

HOW SHOULD THE PRODUCT BE HANDLED

- Impermeable disposable gloves should be worn when administering the product and when handling the gel syringe.

HOW TO ADMINISTER THE PRODUCT

- Place the oral syringe tip between the dog's cheek and gum and press the plunger until the ring-stop causes the plunger to stop after the selected dose (number of "dots" for the dog's weight) has been administered.
- Avoid feeding the dog or giving treats for 15 minutes after administering the gel to avoid swallowing of the gel. If the gel is swallowed it will not work.
- Please visit www.sileodog.com for a comprehensive administration video
- Please see printed support materials and package insert / datasheet for further guidance, and dosing chart.

WHEN TO ADMINISTER AND WHAT SHOULD BE EXPECTED AFTER ADMINISTERING SILEO[®]

- Impermeable disposable gloves should be worn when administering the product and when handling the gel syringe.
- The first dose of Sileo should be given immediately after the dog shows first signs of fear and/or anxiety, or when the typical stimulus (e.g. sound of fireworks) inducing anxiety and/or fear in the dog is detected.
- If the dose is more than 6 dots, it should be divided between both sides of the mouth.
- The drug takes effect after approximately 15 minutes to one hour. The dog should show less intense noise anxiety behaviour, despite the ongoing noise, but should remain fully functional.
- Some dogs might be more sensitive to dexmedetomidine; if the dog appears drowsy, it should be kept warm food or water should not be offered until the effect of the drug has worn off. This will normally happen within a few hours.

WHAT IS THE MINIMUM AGE FOR A DOG TO RECEIVE SILEO[®]?

- Sileo can be administered to dogs as young as 16 weeks of age (up to 17 years of age).

IF NEEDED IS IT POSSIBLE TO GIVE ANOTHER DOSE OF SILEO®?

- If the noise continues and the dog shows signs of anxiety and fear again, further doses can be given at (minimum) intervals of two hours, up to a total of 5 times during each event.
- A partially used syringe can be used again within 14 days after initial opening, if there is enough gel for a complete dose. To minimize the risk of incorrect dosing, a partially used syringe that does not have enough gel for a complete dose should not be used.

WHAT SHOULD BE DONE IF THE DOG HAS SWALLOWED SILEO® GEL

- If the gel is swallowed, it may not be effective. If the dog has swallowed the gel, another dose can be given 2 hours after the previous administration attempt.

WHAT IF SOMEONE GETS THE GEL IN HIS/HER EYES, NOSE OR MOUTH?

- The drug can be absorbed into the body through eyes, nose or mouth. If it comes in contact with the eyes, nose or mouth, flush the affected area 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 the 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. The package information should be shared with the physician and the physician should be told that the product contains an alpha-2 adrenoceptor agonist.

WHAT IF SOMEONE GETS THE GEL ON HIS/HER SKIN

- Impermeable disposable gloves should be worn when administering and handling this product. In case of cuts or chapped skin, the drug can be absorbed into the body. In case of skin contact, the contaminated area should be washed immediately with large amounts of water and contaminated clothing should be removed. A doctor should be contacted in case of any questions or concerns.

WHAT HAPPENS IF I OVERDOSE MY DOG ON SILEO®?

- Signs of sedation may occur when the dose is exceeded. The level and duration of sedation is dose dependent.
- If sedation occurs, the dog should be kept warm.
- Reduced heart rate may be seen after administration of higher than recommended doses of Sileo® gel. Blood pressure decreases slightly below normal levels. Respiration rate can occasionally decrease. Higher than recommended doses of Sileo® gel may also induce a number of other alpha-2 adrenoceptor mediated effects, which include mydriasis, depression of motor and secretory functions of the gastrointestinal tract, temporary AV blocks, diuresis and hyperglycaemia. A slight decrease in body temperature may be observed.

- The effects of dexmedetomidine can be eliminated using a specific antidote, atipamezole (alpha-2 adrenoceptor antagonist). In case of overdose, the appropriate dose of atipamezole calculated in micrograms is 3 times (3X) the dose of administered dexmedetomidine hydrochloride in Sileo[®] gel. Atipamezole (at the concentration of 5 mg/ml) dose in millilitres is one sixteenth (1/16th) of the dose volume of Sileo[®] gel. Each “dot” of Sileo gel is 0.25ml (divide by 16 for appropriate vol/ml of atipamezole)

COMMON ADVERSE EVENTS

- Due to peripheral vasoconstriction, transient paleness of mucous membranes at the application site may be observed.
- Other commonly observed adverse events in clinical trials were sedation and emesis.

CHILD SAFETY

- The package insert carries the warning “keep out of the sight and reach of children”.
- Although it is unlikely children will be exposed to the product a child could gain access to a used or discarded dexmedetomidine gel syringe containing unused product. Measures have been taken to prevent access: The instructions recommend recapping the syringe and returning to the secondary package. The secondary package is child-resistant. If a child did get the syringe out of the package, he/she would have to pull a very tight cap off the tip of the syringe. The child would have to release the tightly locked ring-stop and move it towards the end of the plunger. Only after these actions it is possible to get gel out of the syringe. The high viscosity of the product makes it very difficult to suck gel from the syringe. The child could only receive a significant amount of product in the mouth if the tip of syringe is inside of the mouth when the child depresses the plunger. This oral exposure is considered to be very unlikely. There are no sweet excipients in the gel, reducing the temptation for children to eat it.

CARTON STORAGE

Sileo[®] 0.1 mg/ml oromucosal gel has a shelf life of two (2) years and during storage the syringe should be kept in the outer carton as the product is LIGHT SENSITIVE. Any unused Sileo[®] should be disposed of in accordance with local requirements. This is no different to other standard POM medicines

For further information please contact Zoetis Belgium S.A. (Irish Branch), 2nd Floor, Building 10, Cherrywood Business Park, Loughlinstown, Co. Dublin. TEL: 01 246 9800. www.zoetis.ie.

Use Medicines Responsibly (www.apha.ie).