

CLIENT INFORMATION SHEET

Zeuterin™ (pronounced "zū-tur-in") Injectable Solution for Dogs (Zinc gluconate neutralized by Arginine)

This summary contains important information about Zeuterin™. You should read this information before your dog is injected with Zeuterin™. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information, if you want to know more, or have questions about Zeuterin™.

Zeuterin™ injectable solution is a safe, non-invasive method used to sterilize male dogs 3 months of age and older. It is currently labeled in the US for dogs 3-10 months of age, although labeling for all dogs over 3 months is expected in Spring 2013. Zeuterin™ is given as a single injection with a fine needle into each testicle. The injection should be given only by or under supervision of a licensed veterinarian trained in the proper injection technique.

What happens after my dog is injected with Zeuterin™?

The effectiveness of Zeuterin™ was demonstrated in a field study. In this study, 99.6% of the 224 dogs injected became sterile. Zeuterin™ may not kill all the sperm present at the time of injection in dogs. As with castration or a vasectomy, you should keep your dog away from females in heat for at least 60 days after the injection if you want to ensure no pregnancies.

Unlike surgical castration, dogs treated with Zeuterin™ become sterile without surgical removal of the testicles and, therefore, the male hormone, testosterone, is not completely eliminated. Zeuterin™ may not prevent diseases associated with male hormones, such as prostatic disease or testicular or perianal tumors in dogs, but may reduce the increased risk of other diseases associated with castration such as prostatic cancer.

As with surgical castration, Zeuterin™ may not eliminate male behavior such as roaming, marking, aggression, or mounting in dogs.

What are the possible side effects that may occur in my dog after an Zeuterin™ injection?

Zeuterin™ may cause some side effects. Local and systemic reactions were observed in the field study at a rate of about 1.1%.

Local reactions included testicular swelling (normal reaction to the injection), pain (dogs may resist sitting or may sit with both hind legs open), biting and licking at the scrotum, swelling of the prepuce and irritation, dermatitis, ulceration, infection, dryness or bruising of the scrotum.

Systemic reactions included an increase in the white blood cell count, vomiting, anorexia (loss of appetite), lethargy (tiredness or abnormal attitude), and diarrhea.

Most reactions were seen within the first 7 days after the injection. Pain was most commonly seen in the first 2 days. Vomiting was most commonly seen on the day of the injection (within 1 minute and 4 hours after the injection). You should withhold food for 12 hours prior to injection to help prevent vomiting.

Mild, temporary swelling of the testicles is an expected reaction to the injection which you will notice within 24 - 48 hours after the injection. Your dog's testicles may remain slightly enlarged but non-painful for a few months after the injection.

To minimize the occurrence of adverse reactions, such as scrotal irritation, inflammation or infection, it is critical that you closely monitor your dog's activity post-injection and that you take all precautions necessary to prevent injury to the testicles and to prevent your dog from licking or biting the scrotal area.

For the first few days after injection:

- 1.Restrict your dog's exercise to leash walking.
- 2.Do not allow your dog to run, jump, or engage in play activity.
- 3.Do not allow your dog to lay on hard or wet surfaces.
- 4.Do not allow your dog to lick or bite the scrotal area.

You should contact your veterinarian immediately if you notice that your dog is biting or licking the scrotal area or if you see any signs of redness, discharge or broken skin in the scrotal area.

To report suspected adverse events and/or obtain a copy of the MSDS or for technical assistance, call Ark Sciences, Inc. at 1-800-345-4735. Adverse events can also be reported to the FDA by telephone at 1-888-FDA-VETS or online at <http://www.fda.gov/AnimalVeterinary/SafetyHealth>.

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