



Product Name: Suprelorin 4.7 mg  
APVMA Approval No: 56107/141204

Label Name:	Suprelorin 4.7 mg
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Signal Headings:	PRESCRIPTION ANIMAL REMEDY KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY
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Constituent Statements:	Each implant contains: 4.7 mg Deslorelin (as deslorelin acetate)
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Claims:	<p>[REDUCED CLAIM - CARTON] Implantable slow release Gonadotropin Releasing Hormone (GnRH) analogue. For reduction of testosterone and fertility suppression in sexually mature male dogs. To induce temporary infertility in the prepubertal female dog, not displaying signs of oestrus, between 12 to 16 weeks of age, by delaying first oestrus and preventing pregnancy. To induce temporary infertility and suppress urine odour and sexual behaviour in the intact male cat from 3 months of age.</p> <p>[FULL INDICATIONS - LEAFLET] Suprelorin 4.7 mg is intended to allow choice in the management of fertility in dogs and male cats and can be used as an alternative to surgery.</p> <p>Male dogs For the induction of temporary infertility in healthy, intact, sexually mature male dogs by reduction of testosterone levels. Also aids in the control of unacceptable testosterone-related behaviours (in combination with the appropriate behavioural therapy) and androgen-induced disease such as benign prostatic hyperplasia. Use in the prepubertal male dog has not been investigated.</p> <p>Immature female dogs For the induction of temporary infertility in healthy, intact, sexually immature female dogs, not displaying any signs of oestrus, between 12 and 16 weeks of age, to delay the first oestrus, heat signs and prevent pregnancy at a young age.</p> <p>Male cats For the induction of temporary infertility, suppression of urine odour and sexual behaviours such as libido, vocalisation, urine marking, and aggression in intact male cats from 3 months of age.</p>
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Net Contents:	Two (2) implants preloaded in implanters + 1 multi-use actuator
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Five (5) implants preloaded in implanters + 1 multi-use actuator

Directions for Use:

Restrains:

Contraindications:

Precautions:

Use with caution in breeding male dogs. In some cases there may be a significant delay in return of testosterone production beyond six months and therefore a corresponding delay in return to onset of breeding capacity after a single dose of Suprelorin 4.7 mg. The effect of repeat administration of Suprelorin 4.7 mg on the long term breeding capacity and the onset of return of male dogs to normal fertility after repeat administrations is unknown.

The use of Suprelorin 4.7 mg in sexually mature female dogs to suppress reproductive function and oestrus cycling is not recommended, due to the risk of inducing oestrus, which may cause uterine and ovarian pathology (metropathy, cysts) and unwanted pregnancy. Suprelorin 4.7 mg should only be administered to prepubertal bitches aged 12-16 weeks, which do not display any signs of oestrus. Measurements of hormonal levels and vaginal smears can be used to confirm the absence of oestrus.

The ability of male cats to sire offspring following their return to normal plasma testosterone levels, after the administration of Suprelorin 4.7 mg, has not been fully demonstrated, especially in prepubertal cats. A decision to use Suprelorin 4.7 mg in male cats that are intended to be used for breeding therefore needs to be made on a case by case basis.

Side Effects:

Systemic adverse reactions have not been observed in dogs (n=387) with the use of Suprelorin 4.7 mg (deslorelin) at the recommended dosage. Approximately 1% of treated dogs, those given a 10 times dose, showed some soreness and swelling at the implantation site which resolved over one to two weeks. Undesirable histology has not been found at the site of implantation.

Systemic adverse reactions have not been observed in cats with the use of Suprelorin 4.7 mg (deslorelin) at the recommended dosage. Local reactions consisting of transient redness, swelling and pain or heat on the day of implantation may be observed. Increased sexual activity and roaming may be observed transiently in mature male cats during the first weeks post implantation.

In humans and animals, sexual hormones (testosterone and progesterone) modulate seizure susceptibility. Epileptic seizures have been observed very rarely, with the earliest time to onset of signs reported on the day of implantation, and the latest being 36 weeks after implantation. Seizures were observed in one male dog and one female dog at 5 times the recommended dose. The seizures were controlled using symptomatic treatment.

Prepubertal surgical gonadectomy as well as prepubertal hormonal suppression may delay physeal closure in long bones. Epiphyseal closure, typically without clinical or pathological consequences, at the time of puberty or shortly before, was observed after 73.4 weeks with Suprelorin 4.7 mg and after 60.9 weeks in the non-treated controls.

Dosage and Administration:

Do not use if the foil pouch is broken.

1. Remove Luer Lock cap from the implanter. Attach the actuator to the implanter using the Luer Lock connection.
2. One implant should be placed subcutaneously between the shoulder blades of the dog or cat. Administer one implant only, irrespective of the size of the animal.

3. Select the implant site by locating the area of the back midway between the shoulder blades. It is not necessary to prepare the implantation site. If the hair is long, a small section may be clipped if required.
  4. Lift the loose skin between the shoulder blades. Insert the entire length of the needle subcutaneously. Fully depress the syringe plunger and, at the same time, slowly withdraw the needle. Press the skin at the insertion site as the needle is withdrawn, and maintain pressure for 30 seconds.
  5. Examine the implanter to ascertain that the cylindrical implant (white to pale yellow) has not remained within the syringe or needle, and that the translucent blue spacer is visible. It may be possible to palpate the implant in situ. The biocompatible implant does not require removal.
- Note: The actuator can be re-used.

#### Repeat treatment

Male dogs: Repeat treatment every 6 months to maintain efficacy.

Male cats: Repeat treatment every 12 months to maintain efficacy.

Immature female dogs: Repeat treatment has not been investigated in female dogs and is, therefore, not recommended. The implant should only be used once in immature female dogs and administered between 12 and 16 weeks of age.

#### Onset of fertility

It is necessary to keep treated male dogs away from bitches for 6 weeks following implantation. If repeat implantations are given every six months this caution does not apply for the repeat dose.

It is necessary to keep treated cats away from queens on heat for 6 weeks following implantation. If repeat implantations are given every 12 months this caution does not apply for the repeat dose.

#### Implant loss

In rare instances, the implant may be lost after implantation. It is recommended to monitor for a reduction in testicle size (size reduces by approximately one-third) following Suprelorin 4.7 mg implantation. A testosterone assay may be taken 6 weeks after implantation to check for correct implantation. Scrotal circumference and plasma testosterone should reduce in value under correct implantation. If implant loss is suspected following the first implantation, this can be confirmed in male dogs or cats by observing no reduction in scrotal circumference or plasma testosterone after 6 weeks, as both should reduce in value under correct implantation.

If implant loss is suspected following re-implantation after 6 months in male dogs or 12 months in cats, a progressive increase will be seen in scrotal circumference and/or plasma testosterone will rise to > 1 ng/mL. In both of these circumstances a replacement implant should be administered.

#### General Directions:

Suprelorin 4.7 mg is a synthetic GnRH analogue (deslorelin) in a biocompatible, slow release subcutaneous implant.  
 Suprelorin 4.7 mg is intended to allow choice in the management of fertility in dogs and cats and can be used as an alternative to surgery.  
 Suprelorin 4.7 mg is formulated as a cylindrical implant in a preloaded syringe with an attached needle (implanter).

#### IMPLANT DESCRIPTION

Each implant contains 4.7 mg deslorelin (as deslorelin acetate) in an inert matrix.  
 The implant is a solid, opaque, white to pale yellow cylinder, 2.3 mm x 12.5 mm length.

#### CLINICAL PHARMACOLOGY

Surgical sterilisation, the most common means of preventing breeding in dogs and cats, is not without risk and is not reversible. Suprelorin 4.7 mg, a controlled-release biocompatible implant containing the GnRH agonist deslorelin, acts by suppressing the function of the pituitary-gonadal axis when applied in a low, continuous dose. This suppression results in the failure of treated animals, intact or surgically neutered, to synthesise and/or release

follicle stimulating hormone (FSH) and luteinising hormone (LH), the hormones responsible for the maintenance of fertility as well as secondary sexual behaviours.

#### Male dogs

Infertility using Suprelorin 4.7 mg is achieved in more than 99% of treated male dogs from 6 weeks, and in 97.7% of male dogs for at least 6 months, after the initial treatment. In most cases testosterone levels return to normal 8-10 months post implantation, however it may take a small proportion of dogs 18 months or more. Viable sperm are produced approximately 8 weeks post recovery of normal testosterone.

Use in prepubertal male dogs has not been investigated. It is therefore recommended that male dogs should be allowed to reach puberty before treatment.

#### Prepubertal female dogs

Suprelorin 4.7 mg should only be administered to prepubertal bitches aged 12-16 weeks, which do not display any signs of oestrus. Measurements of hormonal levels and vaginal smears can be used to confirm the absence of oestrus. Repeat treatment has not been investigated and therefore is not recommended.

In one study, 34 females were implanted between 16 and 18 weeks of age. One female implanted at 16-17 weeks of age and two females implanted at 17-18 weeks of age displayed an implant-induced oestrus.

After reaching sexual maturity following the end of the effect of one implant, information was collected about heat cycles and no reproductive safety concerns were noticed. In a follow-up survey, six pregnancies in five bitches were completed. However, due to the limited amount of data, the use in prepubertal bitches intended for breeding should be according to a benefit/risk assessment.

During clinical trials, the first oestrus occurred 6 to 24 months after administration of Suprelorin 4.7 mg in 98.2% of animals; for one out of 56 female dogs (1.8%) suppression of oestrus lasted 5 months. Specifically, 44.6% of female dogs displayed their first oestrus between 6 and 12 months post-implantation, 53.6% between 12 and 24 months post-implantation.

The use in sexually mature female dogs to suppress reproductive function and oestrus cycling is not recommended due to the risk of inducing oestrus, which may cause uterine and ovarian pathology (metropathy and cysts), and unwanted pregnancy.

#### Male cats

In mature male cats, induction of infertility, and suppression of urine odour and sexual behaviours are achieved from approximately 6 weeks up to 12 months after implantation. However, the time course and duration of downregulation after treatment can be variable, with 28 months following implantation being the maximum duration observed for return to fertility.

No data is available in kittens with undescended testicles at implantation. It is recommended to wait until the testicles have descended before administering the product. For most cats, within 2 weeks of implantation, testosterone levels drop, followed by reduced testicular volume and reduced size of penile spines from weeks 4-8 after implantation. Sexual behaviours begin to decrease within a week after treatment, starting with reduced vocalisation, followed by reduction in libido, urine odour, urine marking, and aggressiveness from 4 weeks after implantation.

In 1-3% of male cats, lack of expected efficacy has been reported based on continued expression of sexual behaviours, mating resulting in pregnancy, and/or lack of suppression of plasma testosterone levels. In case of doubt, the animal owner should consider keeping the treated tomcat separate from queens where pregnancy would be undesirable.

When implanted in 3 month old male kittens, suppression of fertility lasted at least 12 months in 100% of cats and > 16 months in 20% of cats. Some sexual behaviours, eg. mounting and neck-biting, may also have a social component but the downregulated male cat cannot complete a mating or induce ovulation in the queen. Clinical effects on urine odour, urine marking, testicular volume, penile spine size and sexual behaviours start to wane after approximately 12 months.

Withholding Periods:

Trade Advice:	
Safety Directions:	
First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.
First Aid Warnings:	
Additional User Safety:	<p>Pregnant women should not administer this product. Those of childbearing age should exercise caution when handling this product. Accidental administration may lead to a disruption of the menstrual cycle. Although skin contact with the implant is unlikely, should this occur, wash the exposed area immediately with soap and water.</p> <p>As with all injectable drugs causing profound physiological effects, routine precautions should be employed by practitioners when handling and using Suprelorin 4.7 mg to prevent accidental injection. In case of accidental human injection, seek medical advice immediately, with a view to having the implant removed. Show the package leaflet or label to the physician.</p>
Environmental Statements:	
Disposal:	<p>Discarded needles should immediately be placed in a designated and appropriately labelled 'sharps' container. The container should be a type to reduce the possibility of injury to handlers during collection and disposal.</p> <p>Retain actuator for use with subsequent implants. Only one actuator is supplied in each box of multiple implants.</p>
Storage:	Store between 2 °C and 8 °C (refrigerate, do not freeze).