

Suprelorin 4.7 mg implant for dogs

Introduction



Qualitative and quantitative composition

4.7 mg deslorelin (as deslorelin acetate)

Pharmaceutical form

White to pale yellow cylindrical implant.

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Clinical particulars

Target species

Dogs (male).

Indications for use

For the induction of temporary infertility in healthy, entire, sexually mature male dogs.

Contra-indications

None

Special warnings for each target species

Infertility is achieved from 6 weeks up to at least 6 months after initial treatment. Treated dogs should therefore still be kept away from bitches on heat within the first six weeks after initial treatment.

One out of 75 dogs treated with the product during clinical trials mated and tied with a bitch on heat within six months of implantation, but this did not result in pregnancy. Should a treated dog mate with a bitch between six weeks and six months after treatment, appropriate measures should be taken to rule out the risk of pregnancy.

Any mating that occurs more than six months after the administration of the product may result in pregnancy. However, it is not necessary to keep bitches away from treated dogs following subsequent implantations, provided that the product is administered every six months.

The ability of dogs to sire offspring following their return to normal plasma testosterone levels, after the administration of the product, has not been investigated.

With respect to testosterone levels (an established surrogate marker of fertility), during clinical trials more than 80 % of dogs administered one or more implants, returned to normal plasma testosterone levels (≥ 0.4 ng/ml) within 12 months of implantation. Ninety-eight percent of dogs returned to normal plasma testosterone levels within 18 months of implantation. However, data demonstrating the complete reversibility of clinical effects (reduced testicular size, reduced ejaculation volume, reduced sperm count and reduced libido) including fertility after six months, or repeated implantation, are limited.

During clinical trials, most of the smaller size dogs (<10 kg) maintained suppressed levels of testosterone for more than 12 months following implantation. For very large dogs (>40 kg), data are limited but duration of testosterone suppression was comparable to that seen in medium and large dogs. The use of the product in dogs of less than 10 kg or more than 40 kg bodyweight, therefore, should be subject to a risk/benefit assessment performed by the veterinarian.

Source: http://www.noahcompendium.co.uk/Virbac_Limited/documents/S5621.html

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Special precautions for use

Special precautions for use in animals

The use of the product in pre-pubertal dogs has not been investigated. It is therefore recommended that dogs should be allowed to reach puberty before treatment with the product is initiated.

Data demonstrate that treatment with the product will reduce the libido of the dog, but other behavioural changes (e.g. male-associated aggression) have not been investigated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Pregnant women should not administer the product. Another GnRH analogue has been shown to be foetotoxic in laboratory animals. Specific studies to evaluate the effect of deslorelin when administered during pregnancy have not been conducted.

Although skin contact with the product is unlikely, should this occur, wash the exposed area immediately, as GnRH analogues may be absorbed through the skin.

When administering the product, take care to avoid accidental self-injection by ensuring that animals are suitably restrained and the application needle is shielded until the moment of implantation.

In case of accidental self-injection, seek medical advice immediately, with a view to having the implant removed. Show the package leaflet or the label to the physician.

Adverse reactions

Moderate swelling at the implant site may be observed for 14 days. Histologically, mild local reactions with chronic inflammation of the connective tissue and some capsule formation and collagen deposition have been seen at 3 months after administration.

A significant decrease in testicle size will be seen during the treatment period. In very rare cases, a testicle may be able to ascend the inguinal ring.

Use during pregnancy, lactation or lay

Not applicable

Interactions

None known

Amounts to be administered and administration route

Subcutaneous use.

The recommended dose is one implant per dog, irrespective of the size of the dog.

Disinfection of the implantation site should be undertaken prior to implantation to avoid introduction of infection. If the hair is long, a small area should be clipped, if required.

Remove Luer Lock cap from the implanter. Attach the actuator to the implanter using the Luer Lock connection.

The product should be implanted subcutaneously in the loose skin on the back between the lower neck and the lumbar area. Avoid injection of the implant into fat, as release of the active substance might be impaired in areas of low vascularisation. Lift the loose skin between the shoulder blades. Insert the entire length of the needle subcutaneously. Fully depress the actuator 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. Examine the syringe and needle to ascertain that the implant has not remained within the syringe or needle, and that the spacer is visible. It may be possible to palpate the implant in situ.

Repeat administration every six months to maintain efficacy.

Do not use the product if the foil pouch is broken.

The biocompatible implant does not require removal. However, should it be necessary to end treatment, implants may be surgically removed by a veterinarian. Implants may be located using ultrasound.

Overdose

No adverse reactions have been observed following simultaneous subcutaneous administration of up to 10 implants.

Withdrawal periods

Not applicable

Pharmacological particulars

Pharmacodynamic properties

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 to synthesise and/or release follicle stimulating hormone (FSH) and luteinising hormone (LH), the hormones responsible for the maintenance of fertility.

The continuous low dose of deslorelin will reduce the functionality of the male reproductive organs, libido and spermatogenesis and lower the plasma testosterone levels, from 4-6 weeks after implantation. A short transient increase in plasma testosterone may be seen immediately after implantation. Measurement of plasma concentrations of testosterone has demonstrated the persistent pharmacological effect of the continuing presence of deslorelin in the circulation for at least six months following administration of the product.

Pharmacokinetic properties

It has been shown that plasma deslorelin levels peak 7 to 35 days following administration of an implant containing 5 mg radiolabelled deslorelin. The substance can be directly measured in the plasma up to approximately 2.5 months post implantation. The metabolism of deslorelin is rapid.

Pharmaceutical particulars

Excipients

Hydrogenated palm oil
Lecithin
Sodium acetate anhydrous

Major incompatibilities

None known

Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

Special precautions for storage

Store in a refrigerator (2°C – 8°C).
Do not freeze.

Immediate packaging

The implant is supplied in a pre-loaded implanter. Each pre-loaded implanter is packaged in a sealed foil pouch, which is subsequently sterilised. The final sales presentation consists of a cardboard carton containing either two or five individually foil wrapped implanters that have been sterilised, together with an implanting device (actuator) that is not sterilised. The actuator is attached to the implanter using the Luer Lock connection.

Disposal

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. The actuator can be re-used.

Marketing authorisation number

EU/2/07/072/001.

Date of the first authorisation or date of renewal

10/07/2007

Date of revision of the text

14/12/2007

Any other information

Nil

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Legal category

POM-V

Significant Changes

[Suprelorin 4.7 mg implant for dogs](#) [Virbac Limited](#) New Product 03/04/2008