



EUROPEAN MEDICINES AGENCY  
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## EPAR summary for the public

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# Suprelorin

## Deslorelin

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the Scientific Discussion (also part of the EPAR).

### What is Suprelorin?

Suprelorin is an implant containing the active substance deslorelin. It is presented in a pre-loaded applicator.

### What is Suprelorin used for?

Suprelorin is used for male dogs and male ferrets to make them temporarily infertile. It is used in healthy, sexually-mature dogs and ferrets that have not been neutered. The implant is inserted subcutaneously, under the loose skin on the back between the lower neck and the lumbar area in dogs and between the shoulder blades in ferrets. Suprelorin starts being effective after about six weeks in dogs and between 5 to 14 weeks in ferrets. The effect continues for six months in the case of the 4.7 mg implant for dogs and 12 months in the case of the 9.4 mg implant for dogs (16 months for ferrets) after which the dog and ferret can be re-implanted if necessary.



## **How does Suprelorin work?**

The active substance in Suprelorin, deslorelin, acts like the natural hormone gonadotropin-releasing hormone (GnRH) which controls the secretion of other hormones involved in fertility. Suprelorin is given as an implant that slowly releases a continuous low dose of deslorelin. This suppresses (blocks) the production of follicle stimulating hormone (FSH) and luteinising hormone (LH). As a result in male dogs and ferrets less testosterone circulates in the blood, the dog and ferret stop producing sperm and its libido is reduced. If a dog or a ferret under treatment with Suprelorin were to mate with a female dog ("bitch") or female ferret ("jill") on heat, the chance of the bitch or jill becoming pregnant would be extremely low.

## **How has Suprelorin been studied?**

Suprelorin has been studied under field conditions in dogs weighing between 10 and 25 kg which were implanted before being followed up for up to a year and in ferrets weighing between 1 and 1.7 kg which were implanted at the beginning of the breeding season before being followed up for up to 6 months. The studies looked at the effect of Suprelorin on blood testosterone levels and the size of the testicles for dogs and ferrets and the ability of the dogs to produce semen for collection. In some of these studies, the dogs and ferrets received Suprelorin more than once and were observed for up to a year after receiving the final implant. The safety of Suprelorin was studied after giving dogs more than 10 times and ferrets more than 6 times the recommended dose rate.

## **What benefit has Suprelorin shown during the studies?**

All studies showed a reduction of testosterone levels in the blood, a reduction in the size of the testicles, decreased libido and decreased spermatogenesis (when fewer sperm are produced by the testicles). In more than 95% of dogs, these effects started at six weeks after implantation and between 5 and 14 weeks in treated ferrets after implantation. The majority of dogs regained normal semen characteristics approximately one year after the last treatment and dogs have been able to successfully mate with bitches, after treatment with Suprelorin was stopped. The return to normal fertility after the end of the treatment has not been investigated in ferrets.

## **What is the risk associated with Suprelorin?**

Dogs can have some moderate swelling at the implant site in the two weeks after implantation. There can also be some local reaction (e.g. inflammation, hardening) for up to three months after implantation. Any swelling or local reaction resolves naturally. Ferrets can have transient moderate swelling, itching and redness at the implant site. Suprelorin is not recommended for use in dogs and ferrets that have not yet reached puberty, as it has not been investigated in these animals. The size of the testicles will decrease during treatment. For a full list of all side effects reported with Suprelorin, see the Package Leaflet.

## **What are the precautions for the person who gives the medicine or comes into contact with the animal?**

This veterinary medicine has been developed especially for dogs and ferrets and is not for use in humans. Although skin contact with the product is unlikely, if this occurs the exposed area should

be washed immediately, as these types of substances may be absorbed through the skin. Pregnant women should not administer the product.

When administering the product, care should be taken to avoid accidental self-injection by ensuring that animals are suitably restrained and that the application needle is shielded until the moment of implantation. In case of accidental self-injection, medical advice should be sought immediately and the Package Leaflet or the label shown to the doctor.

### **Why has Suprelorin been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Suprelorin outweigh its risks for the induction of temporary infertility in healthy, entire, sexually mature male dogs and ferrets and recommended that Suprelorin be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

### **Other information about Suprelorin:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Suprelorin on 10/07/2007. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in March 2012.