**SUPRELORIN® (DESLORELIN) GnRH AGONIST IMPLANTS FOR CONTRACEPTION:**

**RESEARCH INVESTIGATION**

# Agreement of Participation

The AZA Reproductive Management Center (RMC) is sponsoring a basic research study of the efficacy of the gonadotropin-releasing hormone (GnRH) agonist deslorelin in implant form (Suprelorin®). The Center, as part of an agreement with Virbac, Australia, will supply implants to participating AZA-accredited institutions. The RMC will also work with AZA Sustainability Partners to supply implants for animals that are part of an SSP or approved SAFE managed population. The product is approved for sale in the U.S. only for treating ferret adrenal disease and any other use must be for research only. Thus, all participating institutions must agree to submit annual reports to the RMC with information regarding product use. A signed request for an implant will be considered agreement to participate in the research program. Annual terms of participation include:

1) Signed Agreement of Participation

2) Updating animal records through the AZA Reproductive Management Center’s web-based contraception survey ([www.zoocontraceptiondata.org](http://www.zoocontraceptiondata.org))

3) Submission of adverse event/reaction forms to Dr. Ashley Franklin, AZA RMC Program Analyst (franklin@stlzoo.org)

4) Submission of reproductive tissues and tracts to Dr. Dalen Agnew, Reproductive Health Surveillance Program (agnewd@msu.edu)

**Product Information**

Suprelorin® (deslorelin), a GnRH agonist, effects contraception by temporarily suppressing the reproductive endocrine system and preventing production of pituitary (FSH and LH) and gonadal hormones (estradiol and progesterone in females and testosterone in males). The observed effects are similar to those following ovariectomy or castration, but can reverse after the hormone content of the implant is depleted or the implant is removed. As an agonist, deslorelin first stimulates the reproductive system, which can result in estrus and ovulation in females or temporary enhancement of testosterone and semen production in males. Then, down-regulation follows the initial period of stimulation.

Although deslorelin can also be an effective contraceptive in males of some species, it is used primarily in females. Monitoring efficacy by suppression of estrous behavior or of gonadal steroids in feces of females is more straightforward than ensuring continued absence of sperm in males, since most institutions cannot perform regular semen collections. Even after spermatogenesis is interrupted, there may be viable sperm in the ejaculate for weeks or possibly even months, as is the case following vasectomy. It can, however, be used to ameliorate aggression in males of some species, but higher dosages are usually needed.

Trials to date have focused primarily on domestic dogs (Trigg et al. 2001), although there has been one controlled study in domestic cats (Munson et al., 2001) and preliminary data from a number of exotic species (Agnew et al. 2021, Bertschinger et al. 2001 and 2002, Cowl et al. 2018, Guthrie et al. 2021). These investigations have not detected any adverse effects, although weight gain was common, as is often the case following castration or ovariectomy. It has also been successful in reducing aggression in some male primates (e.g., Penfold et al. 2021), but it appears not to be effective in suppressing testosterone or spermatogenesis in some male bovids (e.g., antelope) (Penfold et al. 2002) or marsupials. Recent results from tests of another GnRH agonist in prepubertal domestic cats found that estrous cycles occurred after treatment ended. GnRH agonists should not be used during pregnancy, but may be safe to use during lactation, only after milk production is fully established.

Suprelorin implants are available in two formulations: minimum 6-month (4.7mg) and minimum 12-month (9.4mg) implants. Time to reversal is extremely variable and likely depends on a number of factors, including the animal’s age, the consecutive number of treatments, whether implants were removed, and individual differences in ability to recover physiologically from suppression. Data from various species have shown, though, that individual responses tend to be consistent, that is, if an animal reverses at 8 months it is likely to reverse at 8 months following subsequent treatment. If you cannot wait for signs of reversal to determine duration of efficacy, then for continuous contraception the 4.7-mg implants should be replaced at least every 6 months and the 9.4-mg implants at least every 12 months. Although the implants were not designed to be removed, and they do become more porous and prone to breakage with time as deslorelin diffuses out, the implants do not dissolve. Thus, with careful placement, removal is possible (Cowl et al. 2018) and is recommended to hasten time to reversal. The RMC recommends implant placement in alternative locations to facilitate subsequent removal (Cowl et al. 2018). The ideal site will vary by species, but examples of those that have been successful have been SQ in the fleshy portion at the base of the ear, inner area of the leg (front or rear), and the umbilical area. Although the animal may be able to lick or scratch these areas, deep placement of the implant at the end of a tunnel created by the trocar can protect it. An area with adequate vascularization should be chosen in order to ensure a sufficient dose is absorbed. Fatty, bony, and cartilaginous areas should be avoided in favor of sites with more muscle. An instructional video illustrating implant placement SQ in the inner aspect of the rear leg can be provided on request by contacting contraception@stlzoo.org.

The RMC determines the proper dose for each request based on reports of successful use for each species.

**References**

Agnew, M., Asa, C. S., Franklin, A. D., McDonald, M. M., and Cowl, V. B. (2021) Deslorelin (Suprelorin®) use in North American and European zoos and aquariums: Taxonomic scope, dosing, and efficacy. J Zoo Wildlife Med. 52(2): 427-436.

Bertschinger, H.J., Asa, C.S., Calle, P.P., Long, J.A., Bauman, K., DeMatteo, K., Jöchle, W., Trigg, T.E., and Human, A. (2001) Control of reproduction and sex related behaviour in exotic wild carnivores with the GnRH analogue deslorelin. J. Reprod. Fert., Suppl. 57: 275-283.

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Bertschinger, H. J., Trigg, T. E., Jöchle, W., and Human, A. (2002) Induction of contraception in some African wild carnivores by downregulation of LH & FSH secretion using the GnRH analogue deslorelin. Reproduction, Suppl. 60: 41-52.

Cowl, V. B., Walker, S. L., and Feltrer Rambaud, Y. (2018) Assessing the efficacy of deslorelin acetate implants (Suprelorin) in alternative placement sites. J Zoo Wildlife Med. 49(1): 1-8.

Guthrie, A., Strike, T., Patterson, S., Walker, C., Cowl, V., Franklin, A. D., and Powell, D.M. (2021) The past, present and future of hormonal contraceptive use in managed captive female tiger populations with a focus on the current use of deslorelin acetate. Zoo Biol. 40(4): 306-319.

Munson, L., Bauman, J.E., Asa, C.S., Jöchle, W., and Trigg, T.E. (2001) Efficacy of the GnRH-analogue deslorelin for suppression of the oestrous cycle in cats. J. Reprod. Fert., Suppl. 57: 269-273.

Trigg, T.E., Wright, P.J., Armour, A.F., Williamson, P.E., Junaidi, A., Martin, G.B., Doyle, A.G., and Walsh, J. (2001) Use of a GnRH analogue implant to produce reversible long-term suppression of reproductive function in male and female domestic dogs. J. Reprod. Fert., Suppl. 57: 255-261.

**PARTICIPANT INFORMATION**

**Project: Investigation of the Efficacy of Suprelorin® (deslorelin) Implants for Contraception**

**Sponsor: AZA Reproductive Management Center at the Saint Louis Zoo**

 **for Virbac, Australia**

**Sponsor Contact Information:**

 Ashley Franklin

 Saint Louis Zoo

 1 Government Drive

 St. Louis, MO 63110

 301-956-0171

 franklin@stlzoo.org

**Product Information:**

 Active ingredient: Deslorelin (GnRH agonist)

 Inactive ingredients: various lipids

Dosages: 4.7mg in minimum 6-month matrix or 9.4 mg in minimum 12-month matrix for SQ placement

 (insertion device included); Dosages are assigned by the Reproductive Management Center

 Manufacturer/Source: Virbac, AUS

Costs: $35 per 6-month (4.7mg) implant; $65 per 12-month (9.4mg) implant, to be paid to the Reproductive Management Center as reimbursement, at cost (product is not for commercial sale)

**(Please complete the following)**

**Date**:

**Collaborating Institution:**

**Contact person:** (person responsible for data collection and reporting)

Name:

Mailing address:

Phone/Fax/e-mail address:

**Animal Information:**

Species (genus/species and common name):

Name, Local ID, GAN, and studbook numbers for each individual:

Birth Date(s):

Gender(s):

Body Weight(s):

Date of most recent birth (offspring) for males and females:

Name and email address for the Manager or Curator for this animal:

For non-mammals: explain the reason for this implant request. Please be specific, detailing any past and current medical problems related to the reproductive tract.

**Product Duration of Efficacy Requested** (6-month or 12-month):

**\*Suprelorin is made available by Virbac Australia only for use in the species and number of individuals designated in this agreement.**

**AGREEMENT OF PARTICIPATION**

I, the undersigned, understand that this request is being initiated for an investigational product, Suprelorin® (deslorelin) contraceptive implant, that has not been extensively tested in non-domestic species. As a participant in this study, I will provide information on efficacy and any deleterious effects, including updating this/these animal(s) records on the AZA Reproductive Management Center contraception database website at <http://www.zoocontraceptiondata.org/>.

Signed\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Attending or Chief Veterinarian)

Printed\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(Attending or Chief Veterinarian)

**The AZA Reproductive Management Center is required to submit contact information for the Veterinarian signing this document to FDA. Please fill out the following information:**

**Title:**

 **Email address:**

**Phone Number:**

**Please indicate if you are employed full-time or part-time by the Zoo or Institution where the animal is housed, or if you are a contracted or consulting veterinarian:**

**If contracted or consulting, please provide the name, address and phone number for your primary place of business:**

**SUPRELORIN® (DESLORELIN) CONTRACEPTIVE STUDY**

**INSTRUCTIONS FOR PARTICIPANTS**

**Material Testing Agreement** – Suprelorin® (deslorelin) is made available by Virbac, Australia to the AZA Reproductive Management Center (RMC) for research only in designated species. The RMC must make results of the research available to Virbac. Be sure to see details regarding the reporting requirements below.

**Product Information**– Suprelorin® (deslorelin), a GnRH agonist, effects contraception by temporarily suppressing the reproductive endocrine system and preventing production of pituitary (FSH and LH) and gonadal hormones (estradiol and progesterone in females and testosterone in males). The observed effects are similar to those following ovariectomy or castration, but can reverse after the hormone content of the implant is depleted or the implant is removed. As an agonist, deslorelin first stimulates the reproductive system, which can result in estrus and ovulation in females or temporary enhancement of testosterone and semen production in males. Then, down-regulation follows the initial period of stimulation.

Although deslorelin can also be an effective contraceptive in males of some species, it is used primarily in females. Monitoring efficacy by suppression of estrous behavior or of gonadal steroids in feces of females is more straightforward than ensuring continued absence of sperm in males, since most institutions cannot perform regular semen collections. It can, however, be used to ameliorate aggression in males of some species, but higher dosages are usually needed.

Deslorelin implants are available in two formulations: 4.7mg for a minimum efficacy of 6-months, and 9.4mg for a minimum efficacy of 12-months of contraception. Trials to date have focused primarily on domestic dogs (Trigg et al. 2001), although there has been one controlled study in domestic cats (Munson et al., 2001) and preliminary data from a number of exotic species (Agnew et al. 2021, Bertschinger et al. 2001 and 2002, Cowl et al. 2018, Guthrie et al. 2021). These investigations have not detected any adverse effects, although weight gain was common, as is often the case following castration or ovariectomy. It has also been successful in reducing aggression in some male primates (e.g., Penfold et al. 2021), but it appears not to be effective in suppressing testosterone or spermatogenesis in some male bovids (e.g., antelope) (Penfold et al. 2002) or marsupials.

**Storage and Expiration**– Implants should be stored at refrigeration temperatures (4°C). The expiration date ("place before" date) is stamped on individual implant packages. If the implant would expire prior to placement, contact Ashley Franklin (franklin@stlzoo.org) for advice.

**Implant Insertion**– The area where the implant will be placed should be clipped and cleaned using standard surgical prep techniques. A fold of skin should be lifted and held between the thumb and fingers, as the obturator (supplied with the implant) is inserted. To prevent implant breakage during insertion, create a tunnel with the trocar, then slowly withdraw the obturator, leaving the implant in place in the tunnel. The implant should be held in place through the skin as the obturator is removed to ensure release of the implant so that it remains in place under the skin.

**Implant Placement and Removal**– The implant comes pre-loaded in an insertion device. The Suprelorin® product insert instructs the veterinarian to place the implant subcutaneously (SQ) between the shoulder blades. That site is still appropriate if removal will not be needed, but because removal is desirable in most cases, the RMC recommends implant placement in alternative locations to facilitate subsequent removal (Cowl et al. 2018). The implants were not designed to be removed, and they do become more porous and prone to breakage with time, as deslorelin diffuses out, but they do not dissolve. Thus, with careful placement, removal is possible (Cowl et al. 2018). The ideal site will vary by species, but examples of those that have been successful have been SQ in the fleshy portion at the base of the ear, inner area of the leg (front or rear), and the umbilical area. Although the animal may be able to lick or scratch these areas, deep placement of the implant at the end of a tunnel created by the trocar can protect it. An area with adequate vascularization should be chosen in order to ensure a sufficient dose is absorbed. Fatty, bony, and cartilaginous areas should be avoided in favor of sites with more muscle. An instructional video illustrating implant placement SQ in the inner aspect of the rear leg can be provided on request by contacting contraception@stlzoo.org.

**Tips for Implant Placement:**

1. Identify a location where it is unlikely that the implant will migrate and where the implant can be palpated through the skin.
2. Create a tunnel with the trocar, then slowly withdraw the obturator, leaving the implant in place in the tunnel. The implant should be held steady as the obturator is removed to ensure release of the implant so that it remains in place.
3. Ensure the entire implant is in place by gently palpating, being careful not to crush it, and make note in medical records for future retrieval attempts.
4. At each opportunity, physically palpate the location of the implant to confirm it is in place, again always taking care not to crush the implants, since they become prone to breakage over time.

**Tips for Implant Removal:**

1. Locate implant by palpation, being careful not to crush it.
2. The area should be clipped and cleaned using standard surgical prep techniques.
3. Make a small incision through which the implant can be removed.
4. Grasp implant carefully with forceps and gently remove; even if the implant breaks, attempt to remove all remaining pieces.
5. Confirm that all pieces have been found and removed.
6. Flush area with sterile saline to remove any remaining fragments.
7. Close incision.

**Latency to Effectiveness**– Because the initial effect is to stimulate the reproductive system, it is important to either separate treated animals from opposite sex individuals during the period of enhanced fertility or use another form of contraception. Females treated with deslorelin should be considered fertile for 3 weeks following insertion. Males may remain fertile for up to 2 months, until residual sperm either degenerate or are passed (as following vasectomy).

**Suppression of Initial Estrus/Ovulation**– The estrus and ovulation that can occur within 2 weeks following implant insertion can be suppressed with supplemental progestin treatment for 2 weeks (7 days prior through 7 days after implant insertion). Megestrol acetate (e.g., Ovaban®) tablets are recommended for short-term progestin administration, with the tablet offered as part of a treat. Depo-Provera® should not be substituted for megestrol acetate, because its initial high levels and prolonged release can interfere with Suprelorin® efficacy. MGA implants can be left in place for 1-2 weeks following Suprelorin implant insertion, but then should be removed to prevent interference with the down-regulation action. Leaving them in place longer may compromise Suprelorin® efficacy.

**Signs of Estrus During Contraceptive Treatment**– Suprelorin first stimulates then suppresses estrus in females. Thus, signs of estrus may be seen at the beginning of treatment, particularly when alternative contraception such as Ovaban® (megestrol acetate) is not used to suppress the stimulation phase. Stimulation of estrus and ovulation can increase chances of uterine pathology, especially in carnivores that have an extended luteal phase with elevated progesterone following induced ovulation (e.g., felids, mustelids, and some bears) and following spontaneous ovulation in canids.

**Duration of Efficacy and Reversibility**– The 12-month formulation containing 9.4mg deslorelin is designed to be effective for twice as long as the 4.7mg implants, since the implant matrix releases deslorelin at a slower rate. Thus, the per-kg-body-weight dose for the 9.4mg implants is about twice that of the 4.7mg implants. However, that translates into an equivalent number of implants needed. For example, an animal effectively contracepted for 6 months with two 4.7mg implants will need two 9.4mg implants to achieve contraception for a longer period. That is, one 9.4mg implant will not substitute for two 4.7mg ones.

The minimum duration of efficacy of the 4.7mg implant is 6 months, but the average is about 1 year. For the 9.4mg implants, the minimum duration of efficacy is 12 months but the average is about 2 years. There is considerable variability among species and among individuals, but the response of an individual

tends to be consistent. That is, if an individual reverses at 8 months with a 4.7mg implant, it will likely

always reverse after about 8 months. If it is not possible to wait for signs of reversal to determine

duration of efficacy for the animal, then for continuous contraception the 4.7mg implants should be

replaced at 6-month intervals and the 9.4mg ones at 12-month intervals. These implants were

developed for and have been used primarily in mammals. Duration of efficacy may differ in other taxa.

**Transition phase during reversal** – Data from studies of domestic cats and from African lions (Bertchinger et al. 2008) have identified a transition phase of about 6 months during the process of reversal, when follicles grow and produce estrogen sufficient to stimulate recurring signs of estrus and even mating behavior but without ovulation. In addition, information submitted to the RMC suggests that in some individuals there is sustained stimulation of gonadal hormones (e.g., testosterone in males or higher than normal levels of progesterone following ovulation in females) during reversal.

These observations indicate that reversal is a process that may extend for 6 months or more, when abnormal or irregular cycles may be seen in females or a period of increased aggression may be seen in males. It should be possible to hasten or avoid this process by removing the implant(s) (Cowl et al. 2018). The implant(s) may continue to release deslorelin during this time, at levels too low to maintain pituitary down-regulation but high enough to stimulate gonadal steroid production or, in some individuals, to prevent the LH surge required for ovulation.

**Use during pregnancy**– GnRH agonists should not be used during pregnancy, as they may cause abortion. Even if abortion does not result, deslorelin may interfere with establishment of milk production by impeding proper mammary gland development.

**Use during lactation**– No known contraindications once lactation has been established.

**Use in pre-pubertal individuals or juveniles**– Although data on prepubertal use in wildlife species are limited, studies on domestic kittens and puppies have shown successful postponement of puberty with subsequent documentation of reproductive capacity. As in treatment of adults, there was considerable individual difference in duration of effect. Epiphysial closure was delayed, but body size was not affected.

**Precautions** – In general, the effects on body weight should be similar to those from ovariectomy or castration. Preliminary data indicate that increased appetite will result in weight gain, especially in females, unless food is restricted. In males, muscle loss may result in overall weight loss if not replaced by fat. In sexually dimorphic species, males may become the size (weight) of females. Animals may lose secondary sex characteristics (e.g., lions may lose their manes).

**Consideration for seasonal breeders**– In females of some taxa, GnRH agonists can induce estrus and ovulation even during the non-breeding season. In males, GnRH agonists can transiently stimulate testosterone production even during the non-breeding season. Treatment should begin more than 2 months prior to the anticipated breeding season to prevent initiation of spermatogenesis, because it appears that suppression of sperm production is more easily accomplished before it has commenced.

**General reporting requirements**– All institutions using deslorelin distributed by the RMC must contribute all treatment information for their animals to the RMC's Contraception Database via the web-based contraception survey (<https://www.zoocontraceptiondata.org>) as part of the agreement with Virbac, Australia. ***The product will not be distributed to any institution that fails to complete the survey.*** For questions about the web-based contraception survey, contact Ashley Franklin, AZA RMC Program Analyst (franklin@stlzoo.org).

**Adverse event reporting** – All participants are required to immediately report any adverse effects that might be related to the use of Suprelorin® implants to Ashley Franklin, AZA RMC Program Analyst (franklin@stlzoo.org).

**Health Surveillance Monitoring** – In collaboration with the Reproductive Health Surveillance Program, the RMC conducts pathology surveillance to identify adverse reactions that might be associated with contraceptive products. We are requesting reproductive tracts from all male and female mammals treated with contraceptives, as well as from *non-contracepted individuals,* so we can compare normal changes with lesions arising from contraceptive use*.* Tissue submission instructions can be found at [www.stlzoo.org/RHSP](http://www.stlzoo.org/RHSP). Contact Dr. Dalen Agnew, Michigan State University, at 517-353-1683, agnewd@msu.edu or Dr. Anneke Moresco, moresco2@gmail.com for additional information.

**Fecal Hormone Monitoring** – For those institutions wishing to monitor suppression via fecal gonadal hormones, arrangements can be made with Dr. Corinne Kozlowski, Endocrinologist for the RMC, at 314-646-4762 or kozlowski@stlzoo.org.

**Deslorelin Assay Validation** – The RMC requests that facilities using Suprelorin® implants, which contain deslorelin as the active ingredient, collect serum samples any time the animal is in hand after implant placement to help us establish a database of effective deslorelin concentrations and dynamics. Contact David Powell, AZA RMC Director (dpowell@stlzoo.org) for more information.

**References**

Agnew, M.K., Asa, C.S., Franklin, A.D., McDonald, M.M., Cowl, V.B., 2021. Deslorelin (Suprelorin®) use in North American and European zoos and aquariums: taxonomic scope, dosing, and efficacy. *Journal of Zoo and Wildlife Medicine* 52:427-36.

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Wright, P.J., Verstegen, J.P., Onclin, K., Jochle, W., Armour, A.F., Martin, G.B., and Trigg, T.E. (2001) Suppression of the oestrous responses of bitches to GnRH analogue deslorelin by progestin. *Journal of Reproduction and Fertility, Suppl.* 57:263-268.

**APPENDIX I:**

**COLLECTION, STORAGE AND SHIPMENT OF FECAL SAMPLES**

1. Collect sample as fresh as possible.

2. Scoop up about a spoonful (inexpensive plastic coffee spoons are convenient for this).

3. Place in small zip-lock bag. Do not overfill bag, and make sure it is well sealed.

4. Frequency of collection will vary by species, please contact endocrinologist for recommendation.

5. Using permanent black marker (Sharpie) on white opaque marking area on bag, clearly label with Species, Animal ID, and Date of collection.

6. Freeze immediately. Store at -70°C if possible, but a regular freezer (-20°C) is acceptable for short-term storage (30-60 days).

7. Ship on dry ice by overnight courier to:

 Corinne Kozlowski, Ph.D.

 Research Department

 Saint Louis Zoo

 1 Government Drive

 St. Louis MO 63110

8. Mark box “Frozen Specimens”. Include information in the box clearly identifying species, Deslorelin Study, and contact information for the sender.

9. Before shipping, notify Dr. Corinne Kozlowski (314-646-4762 or kozlowski@stlzoo.org) to expect the package.

10. Costs: $19 per hormone assayed; if 20+ samples are sent at a time the cost is $17 per hormone.