SUPRELORIN F- deslorelin acetate implant
Virbac AH, Inc.

Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.

Suprelorin® F
(DESLORELIN ACETATE) 4.7 mg Implant

LEGAL STATUS - In order to be legally marketed, a new animal drug intended for a minor species must be Approved, Conditionally Approved, or Indexed by the Food and Drug Administration. THIS PRODUCT IS INDEXED - MIF # 900-013. Extra-label use is prohibited. FOR USE IN FERRETS ONLY This product is not to be used in animals intended for use as food for humans or food-producing animals.

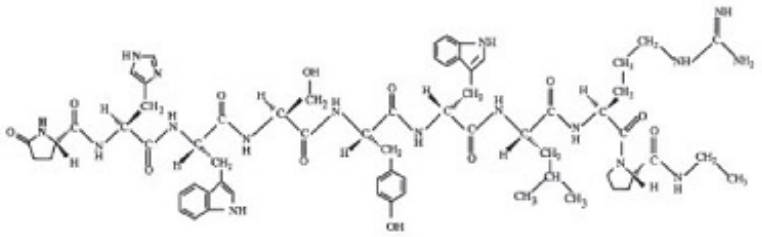
CAUTION

Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Suprelorin® F (4.7 mg) Implant is a synthetic GnRH analogue (deslorelin acetate) in a biocompatible, slow release subcutaneous implant. The implant is a solid, opaque, white to pale yellow cylinder, 2.3 mm x 12.5 mm in length and weighing 50 mg. The Suprelorin® F (4.7 mg) Implant comes pre-loaded in an implanting needle. Each implant contains 4.7 mg deslorelin (as deslorelin acetate) in an inert matrix.

Chemical Structure – Deslorelin acetate



[(6-D-tryptophan-9-(N-ethyl-L-prolinamide)-10-deglycinamide]GnRH

INDICATIONS

Suprelorin® F (4.7 mg) Implant is indicated for the management of adrenal gland cortical disease in the male and female domestic ferret.

DOSAGE AND ADMINISTRATION

The recommended dosage is one, 4.7 mg implant per ferret every 12 months. Appropriate clinical monitoring is suggested to determine that the symptoms of adrenal disease are being adequately controlled.

Do not use if the foil pouch is damaged.

Remove Luer Lock cap from the implanting needle. Attach the actuator syringe to the implanter using the luer lock connection. One implant should be implanting needle subcutaneously at the dorsal aspect of the base of the neck. Administer only one implant per ferret. 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. Lift the loose skin between the shoulder blades. Insert the entire length of the needle subcutaneously. Fully depress the actuator syringe plunger. Press the skin at the insertion site as the needle is slowly withdrawn, and maintain pressure for 30 seconds. Examine the implanting needle to verify that the implant has not remained within the needle, and that the blue plastic spacer is visible at the tip of the needle. It may be possible to palpate the implant *in situ*. The biocompatible implant does not require removal. Wash hands after use.

Repeat treatment every 12 months to maintain efficacy. Appropriate endocrine testing and clinical monitoring should be performed at appropriate intervals to monitor the response to therapy.

CONTRAINDICATIONS

Do not use this product in ferrets with known hypersensitivity to deslorelin acetate or other synthetic hormones.

HUMAN SAFETY WARNINGS

KEEP OUT OF REACH OF CHILDREN. DO NOT HANDLE THIS PRODUCT IF YOU ARE PREGNANT OR NURSING OR SUSPECT YOU MAY BE PREGNANT. Accidental administration may lead to a disruption of the menstrual cycle. Avoid direct skin contact with the implant; if skin contact occurs, wash the affected area immediately with soap and water. The use of gloves is advised. As with all injectable drugs causing profound physiological effects, routine precautions should be employed by practitioners when handling and using Suprelorin® F (4.7 mg) Implant to prevent accidental injection. In case of accidental human injection, a physician should be consulted and the implant should be removed.

PRECAUTION

Do not use in animals intended for breeding. The safe use of this product has not been evaluated in pregnant or lactating ferrets.

ADVERSE REACTIONS

It is possible that treated ferrets will exhibit signs of soreness and swelling at the implantation site which should resolve over one or two weeks. Undesirable histology at the site of implantation has not been reported in other species (canine). Other reported

side effects include: weight gain, lethargy and failure to respond to therapy.

To report suspected adverse drug events, please call Virbac at 800-338-3659. For additional information about adverse drug experience reporting for animal drugs, contact the FDA at 1-888-FDA-VETS or www.fda.gov/reportanimalae.

PHARMACOLOGY

Suprelorin® F (4.7 mg) Implant is a controlled release implant containing the GnRH agonist deslorelin. Deslorelin acetate suppresses the reproductive endocrine system, preventing production of pituitary and gonadal hormones. Deslorelin acetate has not been shown to reduce the size of adrenal tumors and is not considered curative.

DISPOSAL

Each implanting needle (sterile) is a single use device. Used needles should immediately be placed in a designated and appropriately labeled "sharps" container. Each actuator syringe (non-sterile) is a multi-use device and should be saved for future use with the remaining implant(s) in the carton. Unused implants should be disposed of in accordance with local environmental requirements.

STORAGE

Store at temperatures between 2° and 8° C (36° and 46° F). Do not freeze.

HOW SUPPLIED

Five (5) or two (2) implants pre-loaded in implanting needles and individually packaged per carton.

For technical assistance, to request an SDS, or to report suspected adverse drug events, please call Virbac at 1-800-338-3659.

Manufactured for:
Virbac AH, Inc.
P.O. Box 162059
Fort Worth, TX 76161

Product of Australia

MIF 900-013

Revision 11/2020
L-2000-F-US-3

SUPRELORIN F

deslorelin acetate implant

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:51311-444
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
deslorelin acetate (UNII: 679007NR5C) (deslorelin - UNII:TKG3I66TVE)	deslorelin acetate	4.7 mg

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51311-444-05	5 in 1 CARTON		
1		1 in 1 SYRINGE		
2	NDC:51311-444-02	2 in 1 CARTON		
2		1 in 1 SYRINGE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
LEGALLY MARKETED UNAPPROVED NEW ANIMAL DRUGS FOR MINOR SPECIES	MIF900013	09/12/2012	

Labeler - Virbac AH, Inc. (131568396)

Establishment

Name	Address	ID/FEI	Business Operations
Polypeptide Laboratories Inc		962386124	api manufacture

Establishment

Name	Address	ID/FEI	Business Operations
Peptech Animal Health PTY Limited		749040291	analysis, manufacture, pack

Revised: 1/2022 Virbac AH, Inc.