FOR THE USE OF A VETERINARIAN OR
A HOSPITAL OR LABORATORY OR A FARM

Rx Proligestone Injection

DELVOSTERON®

NOT FOR HUMAN USE
FOR ANIMAL TREATMENT ONLY

SCHEDULE H PRESCRIPTION DRUG – CAUTION Not to be sold by retail without the prescription of a Registered Veterinary Practitioner only.

COMPOSITION
Each ml of Delvosteron contains-
Proligestone.....100 mg
Preservatives:
Methyl parahydroxybenzoate.....1.02 mg
Propyl parahydroxybenzoate.....0.12 mg

PHARMACOLOGICAL ACTION
Delvosteron is a long acting progestational agent which has good antigonadotropic properties but is weakly progestagenic and has no androgenic properties. Proligestone has therefore hardly any effect on the endometrium even if it is already sensitized by oestrogens.

INDICATION(S)
The safety of progestogens is related to their molecular structure. Proligestone has a unique molecular configuration which makes it possible to administer the product at any stage of the oestrous cycle with little risk of undesirable effects on the endometrium.

Oestrus control
(i) Bitches
Permanent postponement of heat (repeat injections given in anoestrus/metoestrus induced by the previous administration of the product)
Temporary postponement of heat (a single injection given in anoestrus)
Suppression of heat (a single injection given at the beginning of pro-oestrus)

(ii) Queens
Permanent postponement of calling (repeat injections given in anoestrus/di-oestrus induced by the previous administration of the product)
Temporary postponement of calling (a single injection given during di-oestrus or anoestrus)
Suppression of calling (a single injection given at the onset of calling)

(iii) Ferrets
To prevent the problems, such as vaginal and uterine infection and bone marrow depression associated with prolonged oestrus and persistently high oestrogen levels.

Treatment and prevention of false pregnancy
It has been shown that in most bitches, a single injection of the product will effectively alleviate both the nervous signs and lactation associated with false pregnancy. Trial results have indicated that the incidence of false pregnancy is markedly reduced following the use of the product for oestrus control irrespective of the bitch's previous history in respect of this condition.

Treatment and prevention of feline miliary dermatitis (miliary eczema)

CONTRAINDICATIONS
Do not use in in bitches which are already in oestrus since three days.
Do not use in bitches which have been treated previously with oestrogens or other progestogens for the current false pregnancy.

WARNINGS
Special warnings for each target species:
In animals developing adrenal suppression caused by the administration of the product for permanent postponement of heat, it is recommended to administer glucocorticoids concurrently if the animal is subjected to excessive trauma, stress or a major surgery.
Although the product may be used to medicate bitches at their first oestrus, this regime is not recommended. Similarly medication before a bitch's first oestrus is not generally advised.
As with all progestagens, pre-existing cystic endometrial hyperplasia/pyometra may be activated by treatment with Delvosteron, particularly in bitches injected in proestrus.
When using the product for suppression of heat, it is important to ensure that the bitch is still in the early stages of pro-oestrus as injection given in the later stages of pro-oestrus is unlikely to be effective at suppressing heat.
As cats are seasonally polyoestrus, the recurrence of calling after treatment is very variable. After administration of the product in anoestrus it is likely that calling occurs less often than after administration in proestrus. The return to calling will be further delayed if the non-breeding season (anoestrus) intervenes.

Special precautions for use in animals:
The product has been used to control heat in diabetic animals without altering insulin requirement. However, in other diabetic animals, the administration of the product has led to an increases insulin requirement. It is advised therefore that the product is used with caution in such animals and that insulin blood levels and urine sugar levels are observed carefully during the month after dosing.
In case false pregnancy occurs after the second dose of the product, a conservative treatment (restricted water intake, low carbohydrate diet, increased exercise, etc.) is preferred to further hormone medication.
During suppression of heat treatment in pro-oestrus, bitches may accept the male for some days after treatment. Thus, contact with dogs should be prevented, until the signs of heat, vulval swelling and bleeding have fully regressed. This usually occurs within 5 days of dosing.
When the medicated animal is housed with other bitches, the duration of postponement of oestrus following use of the product may sometimes be shorter than expected.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to proligestone or to any of the excipients should avoid contact with the veterinary medicinal product.
Because proligestone can affect the function of the gonads, it must be administered with precaution to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
The product should not be administered by pregnant women or women that are trying to get pregnant.

Pregnancy:
The use is not recommended (during the whole or part of the pregnancy).
Interaction with other medicinal products and other forms of interaction:
The product should not be administered to bitches which have been treated previously with oestrogens or other progestogens for the current false pregnancy

WITHDRAWAL PERIOD
Not applicable. For use in dogs and cats only.

ADVERSE REACTIONS
A pain reaction may be observed immediately after injection. Slight local reactions (skin thinning, discolouration and alopecia) may occasionally develop at the injection site.
In very rare cases a local or systemic allergic/anaphylactic reaction may occur, necessitating immediate treatment with an appropriate corticosteroid, antihistamine or adrenaline. Most dogs that showed allergic skin reactions responded well to the recommended dose of Covinan/Delvosteron; only in one third of these dogs the allergic reaction persists.
The product, as common with progestogens, may cause adrenal suppression in some animals.
A transient increase in appetite associated with weight gain as well as lethargy may be seen in some animals medicated with the product, but these side effects occur less frequently than with the first generation progestogens such as medroxyprogesterone acetate or megestrol acetate.

As with all progestogens, the possibility exists that the cystic endometrial hyperplasia/pyometra complex may be seen as a side effect of the medication. In the clinical trials carried out with the product, however, the incidence of uterine disorders, including pyometra, was only 0.3 % overall and no cases occurred in bitches injected in pro-oestrus. The incidence of uterine changes was higher (1.4 %) in animals which had previously received depot progestogens containing medroxyprogesterone acetate.
A few cases of mammary gland disorders following the use of the product in entire and neutered queens have been recorded, but proligestone appears less likely to induce the condition than first generation progestogens.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

DOSAGE AND ADMINISTRATION
Delvosteron should be administered by subcutaneous injection taking care that the product is not deposited intradermally or into a pad of subcutaneous fat or scar tissue. Delvosteron should be injected in the neck or on the inside of the thigh.
The usual aseptic precautions should be observed i.e. the site to be used should be cleaned and swabbed with alcohol. It is helpful to massage the injection site following administration to promote dispersion of the product. Shake vial before use. Use a dry sterile needle and syringe.

Bitches: 10-33 mg/kg body weight given by subcutaneous injection. The recommended average dosage is as follows:

Body weight (kg)	Average dose (ml)
<5	1-1.5
5-10	1.5-2.5
10-20	2.5-3.5
20-30	3.5-4.5
30-45	4.5-5.5
45-60	5.5-6.0
>60	10 mg/kg body weight

Cats:
Oestrus control: 1 ml (for the average 3kg body weight) per queen.
Feline miliary dermatitis: 33-50 mg/kg body weight or 1.5 ml per queen.

Dosage schedule:

Bitches
i) Permanent post-ponement of heat

1st injection	– in pro-oestrus (see suppression of heat, below) or in anoestrus (see temporary postponement of heat, below)
2nd injection	– 3 months after 1st injection
3rd injection	– 4 months after 2nd injection
Subsequent injection	– at 5 monthly intervals.

An injection of the product may be given to obtain permanent postponement of heat in bitches that are presented late, provided that postponement has not been interrupted by heat.
Following termination of a permanent postponement course, next oestrus will generally occur within 6-7 months after last injection. In very rare cases, the interval may be less than 5 months and in 7% of the cases it may be longer than 12 months. Very few (<3%) bitches may fail to come on heat again when a permanent postponement course is terminated.

ii) Suppression of heat
A single injection should be administered as soon as possible after signs of pro-oestrus are seen. Following the injection, bleeding, vulval swelling and attractiveness to dogs gradually decrease and stop within 5 days.

iii) Temporary postponement of heat
A single injection may be given at any time during anoestrus but preferably not more than one month before the effect is required. The subsequent oestrus will reoccur on average 6 months after injection. In very rare cases, the interval will be shorter than 3 months or longer than 12 months.

Queens
Oestrus control
Dosages and treatment schedules similar to those given for bitches are advised for permanent postponement, temporary postponement or the suppression of calling. For temporary postponement of calling, the injections may be given either in di-oestrus or anoestrus. Following injection at the onset of calling, heat signs will usually regress within 1-4 days. In a few cases, such a response may not be seen before 7 days.

SIDE EFFECTS AND SPECIAL PRECAUTIONS
See warnings. Brief pain reactions immediately after injection, discoloration and loss of hair at the injection site and endometritis have rarely been observed.

KNOWN SIGNS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
See warnings. Over dosage will delay the period before return to a normal cycle. Treatment is symptomatic.

IDENTIFICATION
White injectable aqueous suspension in a clear glass bottle.

PRESENTATION
20 ml multidose vials.

STORAGE INSTRUCTION
Store below 25°C.
Do not refrigerate. Keep out of reach of children and uninformed persons.
Shelf-life of veterinary medicinal product as packaged for sale : 3 years.
Shelf-life after first opening the container: The product should be used immediately and not stored after opening

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MSD Animal Health

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