RESTRICTED VETERINARY MEDICINE
Keep out of reach of children
FOR ANIMAL TREATMENT ONLY

DELVOSTERON®

INJECTABLE AQUEOUS SUSPENSION OF PROLIGESTONE

Active: Each mL contains 100mg proligestone.

20mL

Read entire label and leaflet before use.

HANDLING PRECAUTIONS Warning. Suspected of causing cancer. Suspected of damage fertility or the unborn child. Wear gloves and wash thoroughly after handling.
FIRST AID If on skin: wash with plenty of soap and water. For advice contact the National Poisons Centre 0800 POISON (0800 764 766) or a doctor.
ACCIDENTAL SELF-INJECTION Obtain medical attention. Show this leaflet and/or SDS.
DISPOSAL Dispose of unused contents in a suitable landfill. Dispose of empty container by burying in a suitable landfill or recycle.


PRESENTATION
A 20 mL vial with a white, aqueous, sterile injectable suspension containing 100 mg/mL proligestone. Preservatives methylhydroxybenzoate 1mg/mL and propylhydroxybenzoate 0.12mg/mL.

USES
The safety of progestagens is related to their molecular structure. Proligestone has a unique molecular configuration which makes it possible to administer Delvosteron at any stage of the oestrus cycle with little risk of undesirable effects on the endometrium.

1. Oestrus control

(i) Bitches
Permanent postponement of heat
Repeat injections given in anoestrus induced by previous administration of Delvosteron.
Temporary postponement of heat
A single injection given during 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/dioestrus induced by the previous administration of Delvosteron.
Temporary postponement of calling
A single injection given during dioestrus or anoestrus.
Suppression of calling
A single injection given at the time of calling.

2. False pregnancy
It has been shown that in most bitches, a single injection of Delvosteron will effectively alleviate both the nervous signs and lactation associated with false pregnancy.

3. Feline Miliary Dermatitis
DOSAGE AND ADMINISTRATION
Shake well before use.

Dosage
(i) Bitches: 10-33 mg/kg bodyweight. The recommended average doses are as follows:

< 5kg: 1.0 - 1.5mL
5-10kg: 1.5 - 2.5mL
10-20kg: 2.5 - 3.5mL
20-30kg: 3.5 - 4.5mL
30-45kg: 4.5 - 5.5mL
≥ 45kg: 6mL

Extremely heavy bitches may require more than 6ml.

(ii) Queens: Oestrus control: 1 mL/3kg (33 mg/kg)
Miliary dermatitis: 1.5 mL/3kg (50 mg/kg)
Repeat after a 2 week interval. Best results are obtained by the concurrent use of an ectoparasiticide. The possible effect on the breeding capacity should be taken into account before using Delvosteron to treat miliary dermatitis.

Route of administration
Delvosteron should be given by subcutaneous injection. The usual aseptic precautions should be observed prior to administration. Massage of the injection site following administration may promote dispersion of the product.

DOSAGE SCHEDULE

(i) Bitches
Permanent postponement of heat
It is recommended that injections are given as follows:

Schedule A: DOSAGE SCHEDULE FOR BITCHES NOT PREVIOUSLY TREATED WITH ANY OTHER PROGESTAGENS

<table>
<thead>
<tr>
<th>Delvosteron injections</th>
<th>First Injection</th>
<th>Second Injection</th>
<th>Third Injection</th>
<th>Subsequent Injections</th>
</tr>
</thead>
<tbody>
<tr>
<td>In anoestrus</td>
<td>3 months after 1st injection.</td>
<td>4 months after 2nd injection.</td>
<td>At 5-month intervals.</td>
<td></td>
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<tr>
<td>OR</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>In pro-oestrus</td>
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</tbody>
</table>

NOTES: If the dosage schedule is interrupted by (pro-)oestrus, schedule A (above) should be applied again starting with 1st injection. Signs in bitches in pro-oestrus will disappear within a few days provided that administration takes place as soon as they become apparent. Unfortunately Delvosteron is not effective in every bitch. Efficacy will decrease as pro-oestrus becomes more advanced. The vast majority of animals will return to heat within 12 months after injection with Delvosteron. A small minority may fail to return to oestrus, but this phenomenon can also be observed in normally cycling, untreated animals on occasion. Fertility of a heat following withdrawal of Delvosteron is not adversely affected.

Schedule B: BITCHES STILL IN ANOESTRUS FOLLOWING TREATMENT WITH OTHER PROGESTAGENS
• Following two or more consecutive injections with another progestagen, treatment with Delvosteron can be continued every 5 months.
• If only one injection with another progestagen has been given, schedule A should be applied starting with 2nd injection.

**Temporary postponement of heat**
A single injection given at any time in anoestrus but preferably not more than one month before the effect is required. The subsequent oestrus will occur on average 6 months after the injection. However, this interval may be as short as 3 months or longer than 12 months in some individuals.

**Suppression of heat**
A single injection as soon as possible after the onset of pro-oestrus is seen (an injection given in later stages of pro-oestrus is unlikely to be effective). Following the injection, bleeding, vulval swelling and attractiveness to dogs should gradually decrease and stop within 5-7 days. Contact with dogs should be avoided until all signs of heat have fully regressed as the bitch may accept the male prior to this. The subsequent oestrus will occur on average 6 months after the injection. However, this interval may be as short as 3 months or longer than 12 months in some individuals.

**Treatment of false pregnancy**
A single dose given as soon as the signs are seen. In most cases, nervous signs will disappear in 6 days and lactation will have stopped or be much reduced by day 9 after injection. In approximately 20% of cases the signs will recur within one month of treatment, about 70% of these cases will respond to a second dose.

(ii) Queens

**Oestrus control**
Dosage regimes similar to those given for bitches are advised for permanent postponement, temporary postponement or the suppression of calling, except that for temporary postponement of calling the injections may be given in either dioestrus or anoestrus. Following injection at the onset of calling, the signs will usually abate within 1-4 days, but in a few cases such a response may not be seen for 7 days. As cats are seasonally polyoestrus, the recurrence of calling after treatment is very variable. However in one study 11% and 30% of cats called within 5 months after medication in anoestrus and pro-oestrus respectively. The return to calling will be further delayed if the non breeding season (anoestrus) intervenes.

**Feline Miliary Dermatitis**
A single injection is often sufficient but a second dose may be given 14 days later if the clinical response is not adequate. Dosing may need to be repeated every 4 months, or more frequently if necessary depending on the clinical response obtained.

**CONTRAINDICATIONS**
Delvosteron should not be used in juvenile bitches to suppress or postpone their first oestrus cycle. Delvosteron may lead to an increase in insulin requirement in diabetic patients.

**SIDE EFFECTS**
Brief pain immediately after injection, discoulouration and loss of hair at the injection site. Atrophy of the skin and underlying tissue has been observed in rare cases.
As with all progestagens, the possibility exists that the Cystic Endometrial Hyperplasia Complex may be seen as a side effect of the medication.
A transient increased appetite, lethargy and weight gain may be seen in some animals medicated with Delvosteron, but these side effects occur less frequently than with the first generation progestagens.
Very occasionally a local or systemic allergic or anaphylactic reaction may occur, necessitating immediate treatment with an appropriate corticosteroid, antihistamine or adrenaline.
In cats a few cases of mammary hyperplasia following the use of Delvosteron have been recorded. False pregnancy may occur following the use of Delvosteron. If this occurs, treat conservatively and avoid further hormone administration.

**NOTES**
It should be borne in mind that in spite of the disappearance of oestrus signs, dogs and cats treated in pro-oestrus may remain fertile for as long as one week. Efficacy can be lower in some large breeds of dog, for example Great Danes.
STORAGE
Store at room temperature, below 25°C. Do not refrigerate or freeze.

ACVM Registration No. A4103. See www.nzfsa.govt.nz/acvm/ for registration conditions

Delvosteron is a registered trademark.

Registered to:
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