PARTICULARS TO APPEAR ON THE OUTER PACKAGE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Delvosteron 100 mg/ml Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains:

Proligestone 100 mg/ml as active and methyl parahydroxybenzoate 1.02 mg/ml and propyl parahydroxybenzoate 0.12 mg/ml as preservatives.

3. PHARMACEUTICAL FORM

Suspension for injection.

4. PACKAGE SIZE

20 ml

5. TARGET SPECIES

Cats, dogs and ferrets.

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake well before use.

Administer by subcutaneous injection.

Dosage per species:

Dog image representative of body weight	<5 kg	1-1.5 ml s.c.
Dog image representative of body weight	5-10 kg	1.5-2.5 ml s.c.
Dog image representative of body weight	10-20 kg	2.5-3.5 ml s.c.
Dog image representative of body weight	20-30 kg	3.5-4.5 ml s.c.
Dog image representative of body weight	30-45 kg	4.5-5.5 ml s.c.
Dog image representative of body weight	45-60 kg	5.5-6.0 ml s.c.
	thereafter	10 mg/kg

Cat image	miliary dermatitis 1.5 ml s.c. oestrus control - 1 ml s.c.

Ferret image	0.5 ml s.c.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry end of:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not refrigerate.

This product should be used immediately and not stored after opening.

Keep the vial in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

FOR ANIMAL TREATMENT ONLY

To be supplied only on veterinary prescription

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF REACH AND SIGHT OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.,

Walton Manor, Walton, Milton Keynes

MK7 7AJ

Licensed distributor N.Ireland:

INTERVET IRELAND Ltd.

Magna Drive, Magna Business Park

Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4321

17. MANUFACTURER'S BATCH NUMBER

Batch No:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Delvosteron 100 mg/ml Suspension for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Contains: Proligestone 100 mg/ml as active and methyl parahydroxybenzoate 1.02 mg/ml and propyl parahydroxybenzoate 0.12 mg/ml as preservatives.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 ml

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous injection

5. WITHDRAWAL PERIOD

Not applicable.

6. BATCH NUMBER

Batch No:

7. EXPIRY DATE

Expiry end of:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

Read the package leaflet before use

For animal treatment only.

The product should be used immediately and not stored after first opening

Keep container in the outer carton.

To be supplied only on veterinary prescription.

POM-V

PACKAGE LEAFLET FOR:

Delvosteron 100 mg/ml Suspension for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder in the UK:

MSD Animal Health UK Ltd.

Walton Manor, Walton, Milton Keynes, Buckinghamshire MK7 7AJ

Marketing authorisation holder in Ireland and Licensed Distributor in Northern Ireland

Ireland:

Intervet Ireland Ltd.

Magna Drive, Magna Business Park, Citywest Road, Dublin 24, Ireland

Manufacturer for the batch release:

Intervet International B.V.

Wim de Korverstaat 35, 5830 AA Boxmeer, The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Delvosteron 100 mg/ml Suspension for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Contains: Proligestone 100 mg/ml as active and methyl parahydroxybenzoate 1.02 mg/ml and propyl parahydroxybenzoate 0.12 mg/ml as preservatives.

4. 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.

False pregnancy: treatment and prevention

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.

Feline miliary dermatitis (miliary eczema): treatment and prevention.

5. CONTRAINDICATIONS

The product is not indicated for use in pregnant animals.

The product should not be administered to bitches which have been treated previously with oestrogens or other progestogens for the current false pregnancy.

Although the product may be used to medicate bitches at their first oestrus, this regime is not normally recommended. Similarly medication before a bitch’s first oestrus is not generally advised.

6. ADVERSE REACTIONS

As with all progestogens, the possibility exists that the CEH/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 transient increased appetite, lethargy and weight gain 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.

A brief pain reaction may be seen immediately after injection. Since a slight local reaction, skin thinning and 'pitting' together with some discolouration and loss of hair may occur very occasionally, it is advisable to inject the product subcutaneously on the medial side of the flank fold in thin skinned or show animals.

Very occasionally a local or systemic allergic/anaphylactic reaction may occur, necessitating immediate treatment with an appropriate corticosteroid, antihistamine or adrenaline.

A few cases of mammary hypertrophy 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. The product, as with other progestogens, may cause adrenal suppression in some animals. It may be sensible therefore to administer glucocorticoids to animals being given the product for the permanent postponement of heat if they are subjected to excessive trauma, stress or require major surgery. However no problems have been reported by veterinary surgeons in practice in this respect.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs, cats and ferrets. For animal treatment only.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Bitches

10-33 mg/kg body weight.

The recommended average doses are as follows:

Bodyweight (kg)	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
thereafter	10 mg/kg

Cats:

Oestrus control - 1 ml for the average 3 kg cat

Feline miliary dermatitis - 33 - 50 mg/kg, or 1.5 ml for the average 3 kg cat

Ferrets: 0.5 ml per jill

Delvosteron should be given by subcutaneous injection taking special care to ensure that the product is not deposited

intradermally or into a pad of subcutaneous fat or scar tissue.

Dosage schedule

Bitches

Permanent postponement of heat:

It is recommended that injections are given as follows:

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 injections at	5 monthly intervals

An injection of Delvosteron may be given to maintain postponement of heat in bitches that are presented late, provided that postponement has not been interrupted by heat.

If anoestrus is not fully maintained, i.e. a ‘breakthrough’ oestrus occurs in bitches on the permanent postponement regime described above, then immediate re-injection is suggested followed by dosing at intervals described above, but starting one step back in the duration of intervals between injections. For example if a breakthrough heat occurs in a bitch being given injections at 5 monthly intervals, an immediate dose is given, the next dose 4 months later and the subsequent doses at 5 monthly intervals. Following termination of a permanent postponement course, the next oestrus will occur generally 6-7 months after the last injection. In approximately 4% of cases the interval may be less than 5 months and in 7% it may be longer than 12 months. Up to 3% of bitches may fail to come on heat again when a permanent postponement course is terminated.

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. In about 3% of cases the interval will be shorter than 3 months and in up to 4% of bitches the delay will be longer than 12 months.

Suppression of heat:

A single injection as soon as possible after the signs of pro-oestrus are seen. Following the injection, bleeding, vulval swelling and attractiveness to dogs gradually decrease and stop within 5-7 days. The times for return to oestrus in the majority of bitches will be 5-6 months on average, but in approximately 3% of bitches the interval will be shorter than 3 months and in 1% it will be longer than 12 months.

Treatment of false pregnancy:

A single dose, given preferably as soon as the signs are seen. In most cases nervous signs will disappear within 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.

Prevention of false pregnancy:

Medication for permanent postponement of oestrus as advocated above.

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 di-oestrus 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.

Treatment and prevention of 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 4 monthly, or more frequently if necessary depending on the clinical response obtained.

Jills

Oestrus control:

Delvosteron can be used to suppress or postpone heat in jills during the breeding season. Following injection in jills showing prolonged oestrus (suppression) the signs will usually abate within 10-11 days. Injections given just before the onset of the breeding season (postponement) or during the breeding season (suppression or postponement) will usually maintain the jill in anoestrus for the remainder of the breeding season.

9. ADVICE ON CORRECT ADMINISTRATION

The usual aseptic precautions should be observed, i.e. the site to be used should be cleansed and swabbed with spirit. It is helpful to massage the injection site following administration to promote dispersion of the product. Shake well before use. Use a sterile needle and syringe.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not refrigerate.

Keep the vial in the outer carton.

Do not use after the expiry date stated on the label and carton after ‘Expiry end of:’

This product should be used immediately and not stored after opening.

12. SPECIAL WARNING(S)

The product has been used to control heat in diabetic animals without altering insulin requirement. However in other animals, the administration of the product has led to an increased insulin requirement. It is advised therefore that the product is used with caution in such animals and that urine sugar levels are observed carefully during the month after dosing.

Cases of false pregnancy that recur after a second dose of the product are better treated conservatively (restricted water intake, low carbohydrate diet, increased exercise, etc) rather than being given further hormone medication.

The product should not be administered to bitches which have been treated previously with oestrogens or other progestogens for the current false pregnancy.

Bitches may accept the male for some days after medication with the product in pro-oestrus (suppression of heat).

Thus contact with dogs should be prevented, wherever possible, until the signs of heat, vulval swelling and bleeding have fully regressed. This usually occurs within 5 days of dosing.

In bitches, the duration of postponement of oestrus following a dose of the product may on occasion be shorter than expected where the medicated animal is housed with other bitches. In such cases contact the marketing authorisation holder for advice on possible alternative dosage regimes.

The product is not indicated for use in pregnant animals.

The product should not be administered to bitches which have been treated previously with oestrogens or other progestogens for the current false pregnancy.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2021

15. OTHER INFORMATION

The product may be safely used in breeding bitches, queens or jills.

Fecundity at the oestrus following the cessation of medication is not adversely affected.

The product is not contra-indicated in bitches with a history of abnormal cycles or those which have shown or are showing signs of urogenital tract disorders. Indeed there is an indication that the product may be used beneficially in such cases; for example the permanent postponement of oestrus with the product may prevent the recurrence of endometritis.

The product generally has little effect on the performance of racing greyhounds.

When using the product for the 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. In trials, 65 % of cases of allergic skin condition in dogs responded well to a single dose of 10-33 mg/kg, as recommended for oestrus control in bitches, although not unexpectedly the response was only maintained in just over one third of the cases.

Cases of flea hypersensitivity responded particularly well.

Dosing with the product may thus be a useful alternative to medication with glucocorticoids whilst the underlying cause is being eliminated.

The product is supplied in 20 ml vials.

POM-V

To be supplied only on veterinary prescription.

Vm 01708/4321

Approved: 01/04/21