

GUIDANCE FOR VETERINARY SURGEONS

Use of norethisterone for oestrus suppression in racing bitches in Great Britain

The Veterinary Medicines Directorate (VMD) has confirmed that norethisterone, an authorised human medication, may be used under the provisions of the Cascade (see 1.3 below) by greyhound veterinarians exercising their clinical judgement to provide long-term suppression of oestrus.

In the light of informed opinion that products currently licensed for oestrus suppression may affect the health and performance of the racing bitch and further that testosterone, as an androgenic anabolic steroid, is considered inappropriate for this purpose on welfare, efficacy and integrity grounds, the GBGB has discussed various options with the VMD

Norethisterone was identified as meeting the requirements of the Cascade and is therefore a candidate for oestrus suppression when authorised products do not produce a satisfactory clinical outcome. Veterinary surgeons may therefore use their clinical judgement on an individual case basis and prescribe norethisterone in racing bitches in Great Britain under the Cascade. Veterinary surgeons are required to record their prescription of norethisterone to a trainer for the treatment of a specific greyhound. However, it is the responsibility of the trainer to ensure that the GBGB Treatment Book is correctly maintained and gives full details of the prescribing veterinary surgeon as required under the GBGB Rules of Racing.

Veterinary surgeons must report to VMD any adverse reactions associated with the use of the currently licensed authorised products to suppress oestrus, and any that may occur when administering norethisterone under the Cascade.

NB. Norethisterone may only be prescribed by a veterinary surgeon. Failure to keep adequate records will be a breach of UK Legislation (Veterinary Medicines Regulations) and a trainer's failure to maintain his/her GBGB Treatment Book satisfactorily will be a breach of the GBGB Rules of Racing. Further it is stressed that the Cascade only permits the use of norethisterone which has a UK Authorisation for human use.

1. UK Legislation (Veterinary Medicines Regulations)

1.1 Possession and storage of norethisterone for use under the Cascade. Legal requirements.

A veterinary surgeon may have in his possession a human medicinal product such as norethisterone intended for administration to animals under the Cascade.

However, an offence is committed if the veterinary surgeon has in his/her possession more product than is proportionate to the amount expected to be used under the Cascade. VMD would expect these quantities to correspond with the records of receipt or supply of these products prescribed under the Cascade.

1.2 Special notes for the use of norethisterone for the suppression of oestrus in racing greyhound bitches

Where a veterinary surgeon concludes that in an individual case, other available methods for control of oestrus are unsuitable for a particular bitch for reasons such as the potential side-effects of using a licensed veterinary preparation (now or for future breeding), he/she may prescribe the human contraceptive progestogen norethisterone for oral use. In this case the following must be recorded by the veterinary surgeon:

- (a) date of examination;
- (b) owner's name and address;
- (c) identification of the animal treated;
- (d) name of the prescribing veterinary surgeon;
- (e) trade name of the product(s) prescribed;
- (f) manufacturer's batch number;
- (g) name and quantity of the active substance;
- (h) quantity prescribed;

Where client or other records contain this information, this will be acceptable. It is not necessary to maintain additional separate records as long as the information is accessible. (Notwithstanding the legal requirements, it is good practice for veterinary surgeons to keep records of all unauthorised and off-label treatments.)

In all cases, veterinary surgeons should explain to clients what they are doing, and why, and secure their agreement to the treatment in the form of written consent.

1.3 The Cascade

The following information is provided by the VMD as an aide memoire. For the prescribing of norethisterone to racing greyhound bitches (b) – LEVEL 2 applies.

1. Where there is no suitable authorised veterinary medicinal product in the United Kingdom for a condition in a particular species, veterinary surgeons may exercise their clinical judgement according to the 'Cascade', whereby they select in the following order:

- (a) LEVEL 1 - a veterinary medicinal product authorised in the United Kingdom for use with another animal species, or for another condition in the same species (off-label use).

If, and only if, there is no such product that is suitable,

- (b) LEVEL 2 - **a medicinal product authorised in the United Kingdom for human use** or a veterinary medicinal product not authorised in the United Kingdom but authorised in another European Member State for use with any animal species

If, and only if, there is no such product that is suitable,

- (c) LEVEL 3 - a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation for the manufacture of that type of product.

- 2. A decision to use a medicine which is not authorised for the condition in the species being treated should not be taken lightly or without justification. In such cases clients should be made aware of the intended use of the unauthorised medicine and given a clear indication of potential side effects. Their consent should be obtained in writing.

1.4 Associated responsibilities

In deciding to use a medicine under the Cascade, a veterinary surgeon must:

- (a) be satisfied that the person who will use the product is competent to use it safely and intends to use it for a use for which it is authorised;
- (b) advise on the safe administration of the product;
- (c) advise as necessary on any warnings or contra-indications on the label or package leaflet; and
- (d) not prescribe more than the minimum quantity required for the treatment. The Veterinary Medicines Regulations do not define 'minimum amount' and the RCVS considers this must be a matter for the professional judgement of the veterinary surgeon in the individual case.
- (e) Veterinary medicinal products must be supplied in appropriate containers and with appropriate labelling.
- (f) *Only UK Authorised norethisterone may be prescribed. Supply and/or use of any product sourced from outside the UK is contrary to Veterinary Medicine Regulations and is illegal.*

1.5 Dispensing guidelines

The following information should be included on labels for products administered under the Cascade. If it is not feasible to include all of the information on the label due to the size of the packaging it must be included on a separate sheet.

- (a) the name and address of the veterinary surgery supplying the veterinary medicinal product;
- (b) the name of the veterinary surgeon who has prescribed the product;
- (c) the name and address of the animal owner;
- (d) the identification of the animal;
- (e) the date of supply;
- (f) the expiry date of the product, if applicable;
- (g) the name or description of the product, including the name and quantity of active ingredients;
- (h) dosage and administration instructions;
- (i) any special storage precautions;
- (j) any necessary warnings for the user, target species, administration or disposal of the product;
- (k) The words “Keep out of reach of children” and “For animal treatment only.”

1.6. Records

Veterinary surgeons are reminded that they should keep a full record of all incoming and outgoing medicinal products and at least once a year carry out a detailed audit reconciling these with stock, recording any discrepancies. The records should be retained for at least 5 years and be made available on request to a duly authorised person.

1.7. Accountability

It is worth stressing that it is the prescribing veterinary surgeon's duty to ensure that they understand the risks of resorting to the Cascade in all its forms; their duty to ensure their client is made aware of the risks; and the need to take due precaution to reduce those risks as far as possible. The advice from the VMD setting out the likelihood of prosecution where a veterinary surgeon does not follow the Cascade rules is not intended to be a threat but an attempt to make veterinary surgeons aware that, should they be challenged about a prescribed medication, their defence could be heard in a court of law. For it is the courts that will ultimately interpret the legislation and the most likely route to the courts will arise through a challenge from

an aggrieved client. At all times therefore, a veterinary surgeon should be prepared to defend their prescription by demonstrating compliance with the law and acceptability of their clinical choice through support from peer or expert opinion. Such defence may not be readily available where a human generic product has been used instead of the authorised veterinary medicinal product.

A medicine prescribed in accordance with the Cascade may be administered by the prescribing veterinary surgeon or by a person acting under their direction. Responsibility for the prescription and use of the medicine remains with the prescribing veterinary surgeon.

2. GBGB Rules of Racing and use of norethisterone

It is a requirement of the GBGB Rules of Racing that an entry is made by the trainer in the GBGB Treatment Book (or other treatment recording system currently in use) clearly recording the name of the dog, the date of administration, the dose and route given and with full details of the veterinary surgeon prescribing norethisterone.

GBGB-licensed veterinary surgeons are reminded that they have a responsibility to read and abide by the Rules of Racing.

Rule 216 Greyhound Treatment Books and Kennel Books

Trainers shall maintain their GBGB Greyhound Treatment Books and GBGB Kennel Books in accordance with the requirements set out in such books.

Rule 217 Administration of medicaments to Greyhounds

A Greyhound when taking part in a Race or Trial must at that time be free of medicines, tonics or substances that could affect its performance or well being, the origin of which could not be traced to normal and ordinary feeding. The only permitted exceptions to this Rule are:-

- i medicinal products which have been authorised by the Veterinary Medicines Directorate for the suppression of a bitch's season, prescribed by a Veterinary Surgeon.
- ii medicinal products which have been authorised by the Veterinary Medicines Directorate as anti-parasitic drugs (for internal/external) parasites or as vaccines.

The application of any substance, for any purpose on a Greyhound in the Racing Paddock, unless supplied, administered by and applied under the direct supervision of a licensed Veterinary Surgeon, is prohibited.

Any tonics, medicaments or other substances administered or applied to a Greyhound by a Trainer or Veterinary Surgeon shall be duly recorded in the Trainer's Greyhound Treatment Book, and that Greyhound must not Race or Trial for seven Days thereafter.

Note for information: Although most prohibited substances will clear the Greyhound's system within seven Days, some products may still be detectable more than seven Days after administration. However, it is the responsibility of Owners and Trainers to satisfy themselves in every case that a Greyhound complies with Rule 217 when taking part in a Race or Trial.

3. Sample Testing

GBGB will continue to sample racing bitches for the presence of norethisterone as part of the Board's Anti-Doping and Medication Control programme. Audits will take place to ensure the prescribing chain is correct and Stipendiary Stewards will be required to notify the Director of Regulation if treatment records have not been maintained. VMD will also be informed so the prescribing veterinary surgeon's records may be checked. *Trainers whose treatment books are incorrectly completed will be liable to disciplinary action.*

4. Contacts

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