

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

10996/013/001

Case No: 7002397

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Intervet Ireland Limited

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

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Nandoral Tablets

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **15/12/2006** until .

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nandoral Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Ethylestrenol 0.500 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

White tablets, 6 mm in diameter, scored and marked SB/4 on one side.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

Ethylestrenol is a testosterone derivative which can be used in the supportive management of chronic renal failure.

4.3 Contraindications

Nandoral tablets should not be given to pregnant animals.

4.4 Special warnings for each target species

Doses of 50 mg daily have been given to dogs for 6-7 months without producing any detectable signs of toxicity. In particular no evidence of liver damage was found. However, where liver function is impaired, close supervision of treatment is always advisable.

4.5 Special precautions for use

Special precaution(s) for use in animals

None.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

4.6 Adverse reactions (frequency and seriousness)

Unduly prolonged dosage or overdosage may cause signs of androgenic activity to appear, especially in entire female animals.

4.7 Use during pregnancy, lactation or lay

Contra-indicated for use during pregnancy.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

Dog and cat, approximately 0.05 mg/kg daily.

e.g. Small dog - 1 tablet daily
 Medium dog - 2 tablets daily
 Large dog - 3-4 tablets daily

The tablets may be administered whole or crushed in food. The daily dosage should be divided and given at evenly spaced intervals. Treatment may be continued almost indefinitely but normally a 10-14 day course is adequate.

As with all hormone therapy there can be considerable variations in response to treatment, the above doses may need to be adjusted according to the clinical response obtained.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Unduly prolonged dosage, or overdosage, may cause signs of androgenic activity to appear, especially in entire female animals.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Ethylestrenol is a testosterone derivative which has very marked anabolic and anti-catabolic action, whilst at the recommended therapeutic dosage it has only weak androgenic or progestagenic activity. It may therefore be used in both male and female with equally safe and potent activity. It encourages nitrogen and calcium retention; it also has strong anti-catabolic effects. Clinically the effects are shown by increased weight gains, improved healing rates of wounds and fractures, increased appetite, alertness and activity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Alpha Tocopherol
 Lactose Monohydrate
 Potato Starch
 Magnesium Stearate

6.2 Incompatibilities

Not applicable.

6.3 Shelf-life

5 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in a dry place protected from light.

6.5 Nature and composition of immediate packaging

Polypropylene container (securitainer) with polyethylene cap and polyurethane inlay each containing 500 tablets.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with any guidance from an appropriate waste regulation authority.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/13/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2002