

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10999/058/001**

Case No: 7006651

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Norbrook Laboratories Limited

Station Works, Newry, Co. Down BT35 6JP

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Norbet 0.25mg Tablets for dogs

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **16/02/2010**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Norbet 0.25mg Tablets for dogs

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Each tablet contains 0.25 mg Betamethasone

Excipients:

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet

A small white tablet.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs.

4.2 Indications for use, specifying the target species

Norbet Tablets are specifically indicated for the treatment of canine allergic dermatoses and arthritic/osteoarthritic conditions.

4.3 Contraindications

Systemic corticosteroid therapy is generally contra-indicated in patients with renal disease and diabetes mellitus.

4.4 Special warnings for each target species

During a course of treatment the clinical situation should be reviewed frequently by close veterinary supervision.

4.5 Special precautions for use

Special precautions for use in animals

Anti-inflammatory corticosteroids such as betamethasone, are known to exert a wide range of side-effects. Whilst single high doses are generally well tolerated, they may induce severe side-effects in long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Steroids themselves, during treatment, may cause Cushingoid symptoms involving significant alteration of fat, carbohydrate, protein and mineral metabolism e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result. During therapy effective doses suppress the Hypothalamo-Pituitreal-Adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment, e.g. dosing to coincide with the time of the endogenous cortisol peak (ie. in the morning with regard to dogs) and a gradual reduction of dosage (for further discussion see standard texts).

Systemically acting corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long term use.

Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis). Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections.

Gastrointestinal ulceration has been reported in animals treated with corticosteroids. GIT ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in corticosteroid-treated animals with spinal cord trauma. Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

4.7 Use during pregnancy, lactation or lay

Corticosteroids are not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion.

4.8 Interaction with other medicinal products and other forms of interaction

Gastrointestinal ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs.

4.9 Amounts to be administered and administration route

The recommended dosage rate is 0.25 mg per 10 kg bodyweight (ie. 1 tablet/10 kg) as an initial dose. At the onset of recovery it is recommended that the dose rate be reduced to the lowest effective level.

The following are recommended average doses for dogs:

5 to 10 kg	(0.125 to 0.25 mg daily)	½ - 1 tablet
10 to 20 kg	(0.25 to 0.50 mg daily)	1 - 2 tablets
20 to 30 kg	(0.50 to 0.75 mg daily)	2 - 3 tablets

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

Not applicable.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Systemic hormonal preparations, excl. sex hormones and insulin, corticosteroids for systemic use, plain, betamethasone.

ATC vet code: QH02AB01

5.1 Pharmacodynamic properties

Betamethasone is a potent synthetic glucocorticoid which is 25 times more potent than cortisol as an anti-inflammatory agent. The mechanism by which corticosteroids exert their effect at cellular level remains unclear however some of the anti-inflammatory activity of corticosteroids could be due to inhibition of prostaglandin synthesis by suppression of the release of arachidonic acid, the prostaglandin precursor, from cell membranes.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose
Lactose
Sodium Starch Glycollate
Povidone K30
Magnesium Stearate

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and composition of immediate packaging

White polypropylene securitubs sealed with white polyethylene caps.
Pack sizes 200 and 1000 tablets.
Not all pack sizes may be marketed

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Ltd.,
Station Works,
Newry,
Co. Down,
Northern Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10999/058/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

16th February 2010

10 DATE OF REVISION OF THE TEXT