

IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10007/007/001**

Case No: 7005973

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:

Boehringer Ingelheim Ltd

Ellesfield Avenue, Bracknell, Berkshire RG12 8YS, England

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:

Voren 14 suspension for injection

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 **30/09/2009**.

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

Voren 14 Suspension for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance

Dexamethasone-21- isonicotinate 3.00 mg

Excipients

Methyl hydroxybenzoate 1.35 mg

Propyl hydroxybenzoate 0.15 mg

For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, cats and dogs.

4.2 Indications for use, specifying the target species

The product is used in the treatment of a wide range of conditions in horses, cats and dogs. For example inflammatory disease of the locomotor and respiratory system and in inflammatory skin conditions.

4.3 Contraindications

Do not use in patients with renal disease and diabetes mellitus.

Do not use for the treatment of laminitis in horses.

Additionally it should be noted that use of the product in horses for other conditions could induce laminitis and careful observations during the treatment period should be made.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

(i) Special precaution(s) for use in animals

It should be noted that use of the product in horses for other conditions could induce laminitis and careful observations during the treatment period should be made.

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

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

Care should be taken to avoid accidental self injection.

4.6 Adverse reactions (frequency and seriousness)

Anti-inflammatory corticosteroids, such as dexamethasone, 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. Steroids, 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.

Systemically administered 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. In the presence of bacterial infection, anti-bacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of disease.

Gastrointestinal ulceration has been reported in animals treated with corticosteroids and g.i.t. 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

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

4.9 Amounts to be administered and administration route

By intramuscular injection. Shake well before use.

Horses: 8 to 12 ml (1 ml per 50 kg bodyweight, i.e. 3 mg dexamethasone per 50 kg bodyweight).

Dogs (over 20 kg): 2 to 3 ml (0.075 ml per kg bodyweight, i.e. 0.225 mg dexamethasone per kg bodyweight).

Cats and small dogs: 0.4 to 2 ml (0.1 ml per kg bodyweight, i.e. 0.3 mg dexamethasone per kg bodyweight).

The first beneficial effects are seen 24 hours after injection.

An appropriately graduated syringe, such as an insulin syringe, must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

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

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.

4.11 Withdrawal Period(s)

Meat: Horses - 6 months.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids for systemic use

ATCvet code: QH02AB02

5.1 Pharmacodynamic properties

Voren 14 has glucogenic, anti-inflammatory and anti-allergic properties.

5.2 Pharmacokinetic properties

Voren 14 contains a potent long acting corticosteroid with a therapeutic effect lasting for approximately 14 days.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate
 Propyl hydroxybenzoate
 Sodium Chloride
 Polysorbate 80
 Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Protect from frost. Do not store above 25°C.

6.5 Nature and composition of immediate packaging

10 ml and 50 ml amber glass multidose vials. Not all pack sizes may be marketed.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Limited
Ellesfield Avenue
Bracknell
Berkshire RG12 8YS
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10007/007/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT