IRISH MEDICINES BOARD ACT 1995

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

(S.I. No. 786 of 2007)

VPA: **10835/035/001**
Case No: 7003761

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:

Novartis Animal Health Ireland Ltd

Industrial Park, **Cork Road**, **Waterford**

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:

PLT Tablets

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 revoked, shall continue in force from **22/01/2008** until **30/09/2009**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: 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

PLT Tablets

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active Substances:

Prednisolone	1.0 mg
Cinchophen	200.0 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.

4 CLINICAL PARTICULARS

4.1 Target Species

Canine

4.2 Indications for use, specifying the target species

For the treatment of osteoarthritis in the dog.

4.3 Contraindications

Not for use in any animal species other than the dog.
Not to be used in animals with the following conditions:

- Pregnancy
- Severe nephrosis
- Circulatory congestive disorders
- Hepatitis
- Previous adverse reaction to a steroid or NSAID treatment.
- Concurrent diuretic therapy or treatment with other NSAID's or steroids.

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

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precaution(s) for use in animals

Should any treated animal show signs of vomiting, diarrhoea, dullness or jaundice, or show no evidence of improvement after 3 days treatment, discontinue therapy.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Anti-inflammatory corticosteroids, such as prednisolone, 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 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. a gradual reduction of dosage (for further discussion see standard texts).

Systemically administered corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retension 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 immuno suppressant actions may weaken resistance to or exacerbate existing infections. In the presence of bacterial infections, antibacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of the 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.

Gastro-intestinal upsets have been reported. Should inappetance or vomiting occur, medication should be discontinued and the dog re-examined by a veterinary surgeon.

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For oral administration with food.

Recommended dosage is based on 25mg cincophen/kg bodyweight and 0.125mg prednisolone/kg bodyweight. This equates to a dose of:

Bodyweight	
8kg	½ tablet twice daily
16kg	1 tablet twice daily
24kg	1½ tablets twice daily
32kg and over	2 tablets twice daily

The dose should be administered with food.

The length of treatment with PLT Tablets depends on the condition treated and the rapidity of response. If there is no improvement within the first 3 days, the dog should be re-examined by the veterinary surgeon. However, an initial treatment period should not exceed 14 days after which the dog's condition should be re-assessed by a veterinary surgeon and a 14 day treatment free interval must be observed before continuing with further treatment. During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

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

No specific treatment.

4.11 Withdrawal Period(s)

Not applicable

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Prednisolone is a glucocorticoid, with widespread anti-inflammatory properties. Cinchophen is a non-steroidal anti-inflammatory drug thought to act principally by inhibition of the cyclooxygenase enzyme responsible for conversion of arachidonic acid into the inflammatory mediators prostaglandins.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Microcrystalline Cellulose
Carmellose Sodium
Povidone
Magnesium Stearate
Calcium Phosphate

6.2 Incompatibilities

None known.

6.3 Shelf-life

The shelf life of unopened product: 24 months
The shelf life after first opening: 3 months

6.4 Special precautions for storage

Do not store above 25°C. Store in dry place, in the original container. Protect from light.

6.5 Nature and composition of immediate packaging

Polypropylene tubs containing 100 or 1000 tablets closed with polyethylene LDPE snap secure lids.

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

Unused product should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Novartis Animal Health Ireland Ltd.
Industrial Park
Cork Road
Waterford
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10835/35/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 2004

10 DATE OF REVISION OF THE TEXT

22nd January 2008