

## **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 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 NSAIDs or steroids.

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

#### **4.4 Special warnings for each target species**

None.

#### 4.5 Special precautions for use

i. Special precautions 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.

ii. Special precautions for the person administering the veterinary medicinal product to animals

None.

iii. Other precautions

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 Hypothalamic-Pituitary-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 minimizing problems of adrenal insufficiency following the withdrawal of treatment, e.g. a gradual reduction of dosage (for further discussion see standard texts).

Systematically 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 the disease.

Gastrointestinal ulceration has been reported in animals treated with corticosteroids and GI tract 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 25 mg cinchophen/kg bodyweight and 0.125 mg prednisolone/kg bodyweight. This equates to a dose of:

##### Bodyweight

|                |                        |
|----------------|------------------------|
| 8 kg           | ½ tablet twice daily   |
| 16 kg          | 1 tablet twice daily   |
| 24 kg          | 1½ tablets twice daily |
| 32 kg 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.

Owing to the prednisolone content, at the end of a treatment period dose levels should be reduced gradually.

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

No specific treatment.

#### **4.11 Withdrawal period(s)**

Not applicable.

## **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group  
Corticosteroids for systemic use, combinations.

**ATC Vet Code:** QH02BX

### **5.1 Pharmacodynamic 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.

### **5.2 Pharmacokinetic particulars**

No information supplied.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Cellulose, microcrystalline  
Carmellose sodium (Ac Di Sol)  
Povidone  
Magnesium stearate  
Calcium phosphate  
Water deionised

### **6.2 Incompatibilities**

Not applicable.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 18 months

### **6.4 Special precautions for storage**

Do not store above 25°C.  
Store in a dry place. Keep the container tightly closed.  
Protect from light.

### **6.5 Nature and composition of immediate packaging**

Polypropylene tablet container containing 100 or 1000 tablets closed with polyethylene child-resistant closure.

Not all pack sizes may be marketed.

**6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products if appropriate**

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

**7. MARKETING AUTHORISATION HOLDER**

Elanco Europe Ltd  
Lilly House  
Priestley Road  
Basingstoke  
Hampshire  
RG24 9NL

**8. MARKETING AUTHORISATION NUMBER**

Vm 00879/4074

**9. DATE OF FIRST AUTHORISATION**

01 December 1992

**10. DATE OF REVISION OF THE TEXT**

September 2016



Approved: 30 September 2016