

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Prednisolone Tablets B.P. (Vet) 1 mg

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Active substance per Tablet:**

Prednisolone 1mg

For full list of excipients, see section 6.1

### **3. PHARMACEUTICAL FORM**

Tablet.

Flat faced, white circular with bevelled edges. One face embossed with letter P and reverse face with a scored half break line, embossed with letters PL above line and with figure 1 below.

### **4. CLINICAL PARTICULARS**

#### **4.1. Target species**

Dog and cat.

#### **4.2 Indications for use**

As an anti-inflammatory and anti-allergenic agent in either species. Prednisolone has found to be useful, often as an adjunct to other agents, in the treatment of tumours.

#### **4.3 Contra-indications**

Administration is contra-indicated where corneal ulceration is present. Administration is generally contra-indicated if renal disease or diabetes mellitus is present.

#### **4.4 Special warnings**

Administration may render concurrent vaccination inoperative.

#### **4.5 Special precautions**

The lowest effective dose should be used. Treatment should not be withdrawn suddenly and in many situations a dosage schedule with falling dose will be found of use. Some cases may require continuing therapy, the minimum effective maintenance dose should be established.

##### **Special precautions for use in animals**

It is generally considered that problems associated with the induction of adrenal insufficiency are minimised by dosing once every alternate morning for dogs and every alternate evening for cats. Following long or medium term treatment the dosage should be reduced gradually.

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

Impermeable gloves should be worn whilst administering the product. Take care to avoid accidental eye contact. If eye contact occurs, wash thoroughly with clean running water. Wash hands after use.

#### **4.6 Adverse reactions**

Prednisolone, as with other corticosteroids, has a wide range of effects. Polydipsia, polyurea and polyphagia are common observations. These side effects often diminish as therapy proceeds. Cushingoid symptoms may be provoked and should be monitored for. Consideration should be given to the potential effects of corticosteroids on wound healing and/or the body's ability to deal with infection. Symptoms of infection may be masked or atypical. Careful consideration should be given as to the desirability of administration to patients with systemic infections, if specific anti-infective is neither possible nor instigated. In the presence of viral infection, corticosteroids may worsen or hasten the progress of the disease. Gastrointestinal ulceration has been reported in animals treated with corticosteroids.

#### **4.7 Pregnancy and lactation**

Prednisolone is not recommended for use in pregnant animals. Administration of corticosteroids in early pregnancy is known to cause foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition.

#### **4.8 Interactions**

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

#### **4.9 Posology**

Generally 0.1-2.0mg/Kg/day. For treatment of tumours 20mg/ m<sup>2</sup> of body surface each other day to 60mg/ m<sup>2</sup> of body surface/day. By oral administration only.

#### **4.10 Overdose**

There is no specific treatment for overdose. Treatment will be largely symptomatic. Gross over dosage might result in immunosuppression. Accompanying cover of antibiotics treatment should be restricted to responses to specific signs and symptoms. Serum electrolytes should be monitored.

#### **4.11 Withdrawal periods**

Not Applicable.

### **5. PHARMACOLOGICAL PROPERTIES**

Prednisolone is a glucocorticoid given in the treatment of various disorders in which corticosteroids are indicated, except adrenal deficiency states. It has relatively slight mineralocorticoid effects.

ATC vet Code: QH02AB06

#### **5.1 Pharmacodynamics**

The action of glucocorticoids in suppressing inflammation may be therapeutic in a variety of conditions. The anti-inflammatory potency of gluconeogenic activity differs between glucocorticoids, that of prednisolone being about four times greater than hydrocortisone but about five times less than betamethasone. Chronic respiratory diseases, severe gastrointestinal disease and inflammatory conditions of the skin and appendages may benefit from glucocorticoid application. Hypersensitivity disorders, auto-immune diseases and some neoplastic conditions may benefit from adjunctive therapy with glucocorticoids. But glucocorticoids can produce symptomatic improvements without treating the underlying disease and the benefits of suppression need to be weighed against the clinical costs of prolonging metabolic or pathological processes or, in the long term, of inducing catabolic effects by the glucocorticoid itself. The immunosuppressive effects may allow progression of intercurrent infectious disease and use of a suitable antimicrobial may be necessary.

#### **5.2 Pharmacokinetics**

Prednisolone is readily absorbed from the gastro-intestinal tract and peak plasma levels are reached within 1 to 2 hours. The half life varies between 2 to 4 hours and the parent plus metabolites are excreted in the urine.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients:**

Lactose Monohydrate  
Maize Starch

Pregelatinised Starch  
Stearic Acid  
Talc Purified  
Magnesium Stearate  
Water Purified

## **6.2 Major incompatibilities**

Not Applicable

## **6.3 Shelf life**

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

## **6.4 Special precautions for storage**

This veterinary medicinal product does not require any special storage conditions.

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

High-density polyethylene containers with low-density polyethylene push-fit, tamper-evident caps containing 500 tablets.

## **6.6 Disposal Advice**

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**

Millpledge Ltd  
Whinleys Estate  
Clarbrough  
Retford  
Nottinghamshire  
DN22 9NA

## **8. MARKETING AUTHORISATION NUMBER**

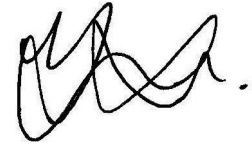
Vm 04409/4002

## **9. DATE OF FIRST AUTHORISATION**

29 August 1997

**10. DATE OF REVISION OF TEXT**

June 2023

A handwritten signature in black ink, consisting of several loops and a long horizontal stroke at the end.

Approved: 27 June 2023