

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 Treatment should not be withdrawn suddenly and in many situations a dosage schedule with falling dose will be found of use.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/ m² of body surface each other day to 60mg/ m² 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
Clarlborough
Retford
Nottinghamshire
DN22 9NA

8. MARKETING AUTHORISATION NUMBER

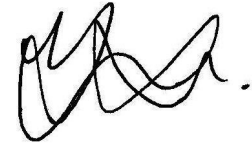
Vm 04409/4002

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 final horizontal stroke.

Approved: 27 June 2023