Clinical particulars

Target species

Dogs and cats.

Indications for use

For the symptomatic treatment or as adjunct treatment of inflammatory and immunemediated diseases in dogs and cats.

Contraindications

Do not use in animals suffering from viral or mycotic infections that are not controlled with an appropriate treatment.

Do not use in animals suffering from diabetes mellitus or hyperadrenocorticism. Do not use in animals with osteoporosis.

Do not use in animals suffering from cardiac or renal dysfunction.

Do not use in animals suffering from corneal ulcers.

Do not use in animals with gastro-intestinal ulceration.

Do not use in animals with burns.

Do not use concomitantly with attenuated alive vaccine.

Do not use in the case of glaucoma.

Do not use during pregnancy (see *Use during pregnancy and lactation*).

Do not use in known cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.

See also *Interactions*.

Special warnings for each target species

Corticoid administration is to induce an improvement in clinical signs rather than a cure. The treatment should be combined with treatment of the underlying disease and/or environmental control.

Special precautions for use in animals

In cases where a bacterial infection is present the product should be used in association with suitable antibacterial therapy.

Because of the pharmacological properties of prednisolone, special care should be taken when the veterinary medicinal product is used in animals with a weakened immune system.

Corticoids such as prednisolone, exacerbate proteinaceous catabolism.

Consequently, the product should be carefully administered in old or malnourished animals.

Corticoids such as prednisolone should be used with caution in patients with hypertension.

Pharmacologically-active dose levels may lead to atrophy of the adrenal cortex, resulting in adrenal insufficiency. This may become apparent particularly after withdrawal of corticosteroid treatment. Adrenal insufficiency may be minimised by institution of alternate-day therapy if practical. The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency (see *Amounts to be administered and administration route)*.

Corticoids such as prednisolone should be used with caution in patients with hypertension, epilepsy, previous steroid myopathy, in immunocompromised animals and in young animals as corticosteroids may induce a delayed growth.

The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of the animals.

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

Prednisolone or other corticosteroids may cause hypersensitivity (allergic reactions).

People with known hypersensitivity to prednisolone or other corticosteroids, or any of the excipients, should avoid contact with the veterinary medicinal product.

To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton.

In case of accidental ingestion, especially by a child, seek medical advice immediately and show the package leaflet or the label to the physician.

Corticosteroids can cause foetal malformations; therefore it is recommended that pregnant women avoid contact with the veterinary medicinal product.

Immediately wash hands thoroughly after handling the tablets.

Adverse reactions

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. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms. The significant dose related cortisol suppression noticed during therapy is a result of effective doses suppressing the hypothalamo-pituitreal adrenal axis. Following cessation of treatment, signs 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.

The significant increase in triglycerides noticed can be a part of possible iatrogenic hyperadrenocorticism (Cushing's disease) involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, increase in body weight, muscle weakness and wastage and osteoporosis may result. Cortisol suppression and an increase in plasma triglycerides is a very common side-effect of medication with corticoids (more than 1 in 10 animals).

The increase of alkaline phosphatase by glucocorticoids could be related to enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

Other changes in blood biochemical and haematological parameters probably associated with the use of prednisolone were significant effects noticed on lactate dehydrogenase (decrease) and albumin (increase) and on eosinophils, lymphocytes (decrease) and segmented neutrophils (increase).

A decrease in aspartate transaminase is also noticed.

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). Corticosteroid use may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease. Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

Other adverse reactions that may occur are: inhibition of longitudinal growth of bones; skin atrophy; diabetes mellitus; euphoria; pancreatitis; decrease in thyroid hormone synthesis; increase in parathyroid hormone synthesis. See also *Use during pregnancy and lactation*.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

Use during pregnancy and lactation

Do not use in pregnant animals. Studies in laboratory animals have shown that administration during early pregnancy may cause foetal abnormalities. Administration during the later stages of pregnancy may cause abortion or early parturition. See *Contraindications*.

Glucocorticoids are excreted in the milk and may result in growth impairment in suckling young animals. Use during lactation only according to the benefit/risk assessment by the responsible veterinarian.

Interactions

Phenytoin, barbiturates, ephedrine and rifampicin, may accelerate the metabolic clearance of corticosteroids resulting in decreased blood levels and reduced physiological effect.

The concomitant use of this veterinary medicinal product with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration. Because corticosteroids can reduce the immunoresponse to vaccination, prednisolone should not be used in combination with vaccines or within two weeks after vaccination.

Administration of prednisolone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypokalaemia may be increased if prednisolone is administered together with potassium depleting diuretics.

Amounts to be administered and administration route

Oral use.

The dose and total duration of treatment is determined by the veterinarian per individual case depending on the severity of symptoms. The lowest effective dose must be used.

Starting dose: 0.5-4 mg per kg body weight per day.

For longer term treatment: when after a period of daily dosing the desired effect has been achieved, the dose should be reduced until the lowest effective dose is reached. The reduction of the dose should be made by alternate day therapy and/or by halving the dose with intervals of 5-7 days until the lowest effective dose is reached.

Dogs should be treated in the morning and cats in the evening on account of differences in day rhythm.

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing. Place the tablet on a flat surface, with its scored side facing up and the convex (rounded) side facing the surface.

Halves: press down with your thumbs on both sides of the tablet.

Quarters: press down with your thumb in the middle of the tablet.

Overdose

An overdose does not cause other adverse effects than those stated in *Adverse reactions*. An antidote is not known. Signs of overdosage should be treated symptomatically.