The SmartPak Pharmacy Equine, and Dog & Cat Product Information Sheet

PrednisTab®

NOTE: This product is FDA-approved for use in dogs only. Using this product in other species is considered extra-label drug use and is permitted when a valid veterinary-client-patient relationship exists and a prescription has been written. Follow your veterinarian's instructions carefully when using this product.

Common Drug Name – Prednisolone

How Supplied by SmartPak – PrednisTab is available in 5mg tablets, 1000-count bottles, and 20mg tablets, 500-count bottles.

Category – Prednisolone is a potent anti-inflammatory steroid.

Caution - Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Indications (Uses) – PrednisTab is intended for use in dogs. The indications for PrednisTab are the same as those for other anti-inflammatory steroids and comprise the various collagen, dermal, allergic, ocular, otic and musculoskeletal conditions known to be responsive to the anti-inflammatory corticosteroids. In acute adrenal insufficiency, Prednisolone may be effective because of its ability to correct the defect in carbohydrate metabolism and relieve the impaired diuretic response to water, characteristic of primary or secondary adrenal insufficiency. However, because this agent lacks significant mineralocorticoid activity, Hydrocortisone or Cortisone should be used when slat retention is indicated.

Dosage and Administration – The dosage recommendations are suggested average total daily doses and are intended as guides. As with other orally administered corticosteroids, the total daily dose of Prednisolone should be given in equally divided doses. The initial suppressive dose level is continued until a satisfactory clinical response is obtained, a period usually of 2 – 7 days in the case of musculoskeletal disease, allergic conditions and ocular inflammatory diseases. If a satisfactory response is not obtained in 7 days, reevaluation of the case to confirm the original diagnosis should be made. As soon as a satisfactory clinical response is obtained, the daily dose should be reduced gradually, either to termination of treatment in the case of acute conditions or to the minimal effective maintenance dose level in the case of chronic conditions. In chronic conditions, it is important that the reduction in dosage from initial to maintenance dose levels be accomplished slowly. The maintenance dose level should be adjusted from time to time as required by fluctuation in the activity of the disease and the animal's general status.
Dosage: 2.5mg/10lb body weight per day.

Contraindications – Do not use in viral infections. Prednisolone, like Methylprednisolone, is contraindicated in animals with peptic ulcer, corneal ulcer and Cushingoid syndrome. The presence of diabetes, osteoporosis, predisposition to thrombophlebitis, hypertension, congestive heart failure, renal insufficiency and active tuberculosis necessitates carefully controlled use. Some of the above conditions occur only rarely in dogs, but should be kept in mind.

Caution – Because of its inhibitory effect on fibroplasias, Prednisolone may mask the signs of infection and enhance dissemination of the infecting organism. Hence, all animal patients receiving Prednisolone should be watched for evidence of intercurrent infection. Should infection occur, it must be brought under control by use of appropriate antibacterial measures, or administration of Prednisolone should be discontinued.

Warning – Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta and metritis. Additionally, corticosteroids administered to dogs, rabbits and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies, including deformed forelegs, phocomelia and anasarca.

Human Warnings – Not for use in humans. Keep out of reach of children.

Precautions –Because this anti-inflammatory steroid manifests little sodium-retaining activity, the usual early sign of Cortisone or Hydrocortisone overdosage (i.e. increase in body weight due to fluid retention) is not a reliable index of overdosage. Hence, recommended dose levels should not be exceeded, and all animal patients receiving Prednisolone should be under close medical supervision. All precautions pertinent to the use of Methylprednisolone apply to Prednisolone. Use of corticosteroids, depending on dose, duration and specific steroid, may result in inhibition of endogenous steroid production following drug withdrawal. In patients presently receiving or recently withdrawn from systemic corticosteroid treatments, therapy with a rapid-acting corticosteroid should be considered in unusually stressful situations.

Adverse Reactions (side effects) – Prednisolone is similar to Methylprednisolone in regard to kinds of side effects and metabolic alterations to be anticipated when treatment is intensive or prolonged. In animal patients with diabetes mellitus, use of Prednisolone may be associated with an increase in insulin requirement. Negative nitrogen balance may occur, particularly in animals that require protracted maintenance therapy; measures to counteract persistent nitrogen loss include a high protein intake and the administration, when indicated, or a suitable anabolic agent. Excessive loss of potassium, like excessive retention of sodium, is not likely to be induced by effective maintenance doses of Prednisolone. However, these effects should be kept in mind and the usual regulatory measures employed as indicated. Ecchymotic manifestations in dogs may occur. If such reactions do occur and are serious, reduction in dose or discontinuance of Prednisolone therapy may be indicated. Side effects such as enzyme elevations, weight loss, anorexia, polydipsia and polyuria have occurred following the use of synthetic corticosteroids in dogs. Vomiting and diarrhea (occasionally bloody) have also been observed. Cushing's syndrome in dogs has been reported in association with prolonged or repeated steroid therapy. Since Prednisolone, like Methylprednisolone, suppresses endogenous adrenocortical activity, it is highly important that the animal patient receiving Prednisolone be under careful observation, not only during the course of treatment, but for some time after treatment is terminated. Adequate adrenocortical supportive therapy with cortisone or hydrocortisone, and including ACTH, must be employed promptly if the animal is subjected to any unusual stress such as surgery, trauma or severe infection.

Storage Conditions:
Store at controlled room temperature 59 – 86F.

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