SMARTPAK[™] The SmartPak[™] Pharmacy Dog and Cat Product Information Sheet

Atopica®

Common Drug Name - Cyclosporine

How Supplied by SmartPak- Atopica capsules are available in 10, 25, 50 and 100mg strengths in daily dose SmartPaks and in 15 unit-dose blisters.

Category – Atopica is an immunosuppressive agent.

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

Indications (Uses) – For the control of atopic dermatitis in dogs at least 6 months in age and weighing at least 4 lbs body weight.

Dosage and Administration -

The initial daily dose of Atopica is 5mg/kg/day (3.3-6.7mg/kg/day) as a single daily dose for 30 days. Following this initial daily treatment period, the dose may be tapered by decreasing the frequency of dosing to every other day or two times a week, until a minimum frequency is reached which will maintain the desired therapeutic effect. Atopica should be given at least one hour before or two hours after a meal. If a dose is missed, the next dose should be administered (without doubling) as soon as possible, but dosing should be no more frequent than once daily.

Contraindications – Atopica is not for use in dogs with a history of malignant neoplasia.

Human Warning – Not for human use. Keep out of reach of children.

Warning - For use only in dogs.

Precautions – GI problems and gingival hyperplasia may occur at the initial recommended dose. Simultaneous administration of Atopica with drugs that suppress the P-450 enzyme system, such as Ketoconazole, may lead to increased plasma levels of Cyclosporine. The safety and effectiveness of Atopica has not been established in dogs less than 6 months of age or less than 4 lbs body weight. Atopica is not for use in breeding dogs, pregnant or lactating bitches. There have been reports of convulsions in human adult and pediatric patients receiving Cyclosporine, particularly in combination with high dose Methylprednisolone. Killed vaccines are recommended for dogs receiving Atopica because the impact of Cyclosporine on the immune response to modified live vaccines is unknown.

Adverse Reactions (Side Effects) -

Vomiting and diarrhea were the most common adverse reactions occurring during the study. Persistent otitis externa, urinary tract infections, anorexia, gingival hyperplasia, lympadenopathy and lethargy were the next most frequent adverse events observed.

Storage Conditions: Store and dispense in the original unit-dose container at controlled room temperatures between 59 – 77F.

Manufactured for:

Novartis Animal Health US, Inc. Greensboro, NC 27408

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