



Sporimune™ (cyclosporine capsules) USP MODIFIED

Brief Summary (For Full Prescribing Information, see package insert)

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian. Keep this and all drugs out of reach of children.

Description: Sporimune (cyclosporine capsules) USP MODIFIED is an oral form of cyclosporine that immediately forms a microemulsion in an aqueous environment. Cyclosporine, the active ingredient in Sporimune, is a cyclic polypeptide, immune modulating agent consisting of 11 amino acids. It is produced as a metabolite by the fungal species *Beauveria nivea*.

Indications: Sporimune is indicated for the control of atopic dermatitis in dogs weighing at least 4 lbs. (1.8 kg) body weight.

Contraindications: Sporimune is contraindicated for use in dogs with a history of neoplasia. Do not use in dogs with a hypersensitivity to cyclosporine.

Warnings: Sporimune is a systemic immunosuppressant that may increase the susceptibility to infection and the development of neoplasia.

Human Warnings: Not for human use. Keep this and all drugs out of reach of children. **For use only in dogs. Capsules should not be broken or opened.** Wear gloves during administration. **Wash hands after administration.** In case of accidental ingestion, seek medical advice immediately and provide the package insert or the label to the physician.

Precautions: The safety and effectiveness of Sporimune has not been established in dogs less than 6 months of age or less than 4 lbs body weight. Sporimune is not for use in breeding dogs, pregnant or lactating bitches. As with any immunomodulation regimen, exacerbation of sub-clinical neoplastic and infectious conditions may occur. Gastrointestinal problems and gingival hyperplasia may occur at the initial recommended dose. Sporimune may cause elevated levels of serum glucose, and should be used with caution in cases with diabetes mellitus. If signs of diabetes mellitus develop following the use of Sporimune, consideration should be given to tapering or discontinuing the dose. Sporimune should be used with caution with drugs that affect the P-450 enzyme system. Simultaneous administration of Sporimune with drugs that suppress the P-450 enzyme system, such as azoles (e.g. ketoconazole), may lead to increased plasma levels of cyclosporine. Since the effect of cyclosporine use on dogs with compromised renal function has not been studied, Sporimune should be used with caution in dogs with renal insufficiency. 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 Sporimune because the impact of cyclosporine on the immune response to modified live vaccines is unknown (See Animal Safety).

Adverse Reactions: A total of 265 dogs were included in the field study safety analysis. Vomiting and diarrhea were the most common adverse reactions occurring during the study.

Post-Approval Experience (Rev 2014): The following adverse events are based on post-approval adverse drug experience reporting. Not all adverse reactions are reported to FDA CVM. It is not always possible to reliably estimate the adverse event frequency or establish a causal relationship to product exposure using this data. The following adverse events are grouped by body system and are presented in decreasing order of reporting frequency.

Gastrointestinal: Emesis, diarrhea, gingival hyperplasia, hemorrhagic diarrhea, abdominal pain, hematemesis, digestive tract hemorrhage, hypersalivation, retching, flatulence, tenesmus, intestinal stasis, digestive tract hypermotility, melena, pancreatitis, involuntary defecation

General: Lethargy, anorexia, weight loss, polydipsia, hyperthermia, pale mucous membrane, general pain, collapse, dehydration, edema
Dermatologic: Pruritus, dermatitis and eczema, alopecia, erythema, papilloma, bacterial skin infection, skin lesion, skin and/or appendage neoplasm, pigmentation disorder, hair change, hyperkeratosis, histiocytoma, fungal skin infection, dermal cyst(s), desquamation

Behavioral: Hyperactivity, behavioral changes, anxiety, vocalization, aggression, inappropriate urination, disorientation

Neurologic: Muscle tremor, convulsion, ataxia, paresis
Respiratory: Tachypnea, dyspnea, cough

Urologic: Polyuria, urine abnormalities (hematuria, urinary tract infection, proteinuria, glucosuria, decreased urine concentration), urinary incontinence, cystitis, renal failure, renal insufficiency

Immune: Urticaria, anaphylaxis, allergic edema
Blood and lymphatic: Lymphadenopathy, anemia, hypoalbuminemia, leukopenia

Hepatic: Elevated Liver Enzymes, hepatopathy, hepatomegaly, hepatitis

Musculoskeletal: Lameness, limb weakness, myositis
Ear and labyrinth: Otitis externa

Cardio-vascular: Tachycardia

Endocrine: Diabetes mellitus, hyperglycemia

In some cases, death/euthanasia has been reported as an outcome of the adverse events listed above. Neoplasms have been reported in dogs taking cyclosporine, including reports of lymphoma/lymphosarcoma and mast cell tumor. It is unknown if these were preexisting or developed de novo while on cyclosporine. Diabetes mellitus has been reported; West Highland White Terriers are the most frequently reported breed.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Dechra Veterinary Products at (866) 933-2472.

For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or <http://www.fda.gov/reportanimalae>

Manufactured For:

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NAVCI Institute 2024: It's IN the Details

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The NAVC Institute offers a smaller, more extensive continuing education experience compared to the large, fast-paced CE conferences throughout the veterinary landscape. In addition to providing a more intimate setting, the NAVC Institute offers the chance for team courses, allowing for veterinarians and veterinary nurses to participate in the same class and learn how to build clinical skills together. And new this year, practice managers are invited to attend a course designed specifically for them.

The NAVC Institute 2024, taking place this May 20 to 24 in Orlando, Florida, will feature topics such as small animal abdominal ultrasonography (general and intermediate), ophthalmology (general and advanced), orthopedic surgery techniques, soft tissue surgery techniques, and strategic leadership for veterinary practice managers.

Attendees will be able to earn 16 to 32 CE credit hours per selected course. Registration will also include course notes, lodging, meals, Expo Hall access, an NAVC publications subscription, a free VetFolio individual annual subscription, and free registration to VMX 2025!

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