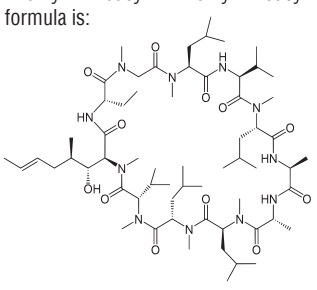
Modulis® for Cats
(cyclosporine oral solution) USP MODIFIED
100 mg/mL
10758

Modulis® for Cats
(cyclosporine oral solution) USP MODIFIED
100 mg/mL
10758

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

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

Chemically, cyclosporine A is designated Cyclo[[(E)-(2S, 3R, 4R)-3-hydroxy- 4-methyl-2-(methylamino)-6-octenoyl]-L-2-aminobutyryl -N-methylglycyl- N -methyl-L-leucyl-L-valyl-N-methyl-L-leucyl-L-alanyl-D-anayl-N-methyl -L- leucyl- N-methyl-L-leucyl-N-methyl-L-valyl]. The structural formula is:



Indication:
MODULIS® for Cats is indicated for the control of feline allergic dermatitis as manifested by excoriations (including facial and neck), miliary dermatitis, eosinophilic plaques, and self-induced alopecia in cats at least 6 months of age and at least 3 lbs (1.4 kg) in body weight.

Dosage and Administration:
Always provide the Instructions for Assembling the Dispensing System and Preparing a Dose of MODULIS® for Cats and the Information for Cat Owners with prescription.
The initial dose of MODULIS® for Cats is 3.2 mg/lb/day (7 mg/kg/day) as a single daily dose for a minimum of 4 to 6 weeks or until resolution of clinical signs. Following this initial daily treatment period, the dose of MODULIS® for Cats may be tapered by decreasing the frequency of dosing to every other day or twice weekly to maintain the desired therapeutic effect. MODULIS® for Cats should be administered directly on a small amount of food or orally just after feeding. Whenever possible, MODULIS® for Cats should be administered on a consistent schedule with regard to meals and time of day. 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.

The dispensing system includes an oral dosing syringe graduated in 1 lb increments. To dose the cat, the syringe should be filled to the nearest 1 lb corresponding to the cat's body weight (round down if 0.1 to 0.4 lb, round up if 0.5 to 0.9 lb). Each pound graduation on the syringe delivers a volume of 0.032 mL providing 3.2 mg/lb. **Do not rinse or clean the oral dosing syringe between uses.** (See **Instructions for Assembling the Dispensing System and Preparing a Dose of MODULIS® for Cats**)

Contraindications:
Do not use in cats with a history of malignant disorders or suspected malignancy. Do not use in cats infected with feline leukemia virus (FeLV) or feline immunodeficiency virus (FIV).
Do not use in cats with a hypersensitivity to cyclosporine.

Warnings:
MODULIS® for Cats is a systemic immunosuppressant that may increase the susceptibility to infection and the development of neoplasia. One of 205 field study cats died of the effusive form of feline infectious peritonitis. (See **Adverse Reactions**)

Persistent, progressive weight loss that resulted in hepatic lipidosis occurred in 2 of 205 cats on treatment with cyclosporine in field studies. Monitoring of body weight is recommended. (See **Adverse Reactions**)

Human Warnings:
Not for human use. Keep this and all drugs out of reach of children. **For use only in cats.**

Special precautions to be taken when administering MODULIS® for Cats:
Do not eat, drink, smoke, or use smokeless tobacco while handling MODULIS® for Cats.
Wash hands after administration.
In case of accidental ingestion, seek medical advice immediately and provide the package insert or the label to the physician.
People with known hypersensitivity to cyclosporine should avoid contact with MODULIS® for Cats.

Precautions:
The safety and effectiveness of MODULIS® for Cats has not been established in cats less than 6 months of age or less than 3 lbs (1.4 kg) body weight.

MODULIS® for Cats is not for use in breeding cats, pregnant or lactating queens.

Cats should be tested and found to be negative for FeLV and FIV infections before treatment.

As with any immunosuppressive regimen, exacerbation of sub-clinical neoplastic and infectious conditions may occur. MODULIS® for Cats is not for use with other immunosuppressive agents.

Cats that are seronegative for *Toxoplasma gondii* may be at risk of developing clinical toxoplasmosis if they become infected while under treatment, which can be fatal. In a controlled laboratory study, cats seronegative for *T. gondii* were administered cyclosporine and subsequently infected with *T. gondii*, resulting in increased susceptibility to infection and subsequent expression of toxoplasmosis.
Cyclosporine did not increase *T. gondii* oocyst shedding (see **Animal Safety**). Potential exposure of seronegative cats to *T. gondii* should be avoided (e.g. keep indoors, avoid raw meat or scavenging).

In cases of clinical toxoplasmosis or other serious systemic illness, stop treatment with cyclosporine and initiate appropriate therapy.

MODULIS® for Cats may cause elevated levels of serum glucose, creatinine, and urea nitrogen. MODULIS® for Cats should be used with caution in cases with diabetes mellitus or renal insufficiency.

MODULIS® for Cats should be used with caution with drugs that affect the P-450 enzyme system. Simultaneous administration of MODULIS® for Cats with drugs that suppress the P-450 enzyme system, such as azoles (e.g. ketoconazole), may lead to increased plasma levels of cyclosporine.

Treatment with MODULIS® for Cats may result in decreased immune response to vaccination. Naïve cats may not develop protective titers during treatment (see **Animal Safety**).

Adverse Reactions:
The clinical safety of cyclosporine was assessed in a masked, controlled 6-week field study followed by a 12-week open-labeled dose-tapering field study. In these two field studies, 205 cats received treatment with cyclosporine for up to 126 days.

Two cats died or were euthanized within two weeks following study exit. One cat was diagnosed with the effusive form of feline infectious peritonitis and died following normal study exit, and one cat with pre-existing anemia that worsened during the study was diagnosed with aplastic anemia and euthanized because of a poor prognosis for recovery.

Fourteen of the 205 cats (6.8%) were withdrawn from the studies due to the occurrence of an adverse reaction. Adverse reactions in these 14 cats included weight loss, anorexia, vomiting, diarrhea, hypersalivation, lethargy, hepatic lipidosis and jaundice, upper respiratory signs, ocular discharge, cough, toxoplasmosis, lymphopenia, anemia, bacterial dermatitis, seizure, ataxia, and small cell gastrointestinal lymphoma.

The most commonly reported adverse reaction was vomiting. In most cases, vomiting spontaneously resolved with continued dosing. Adverse reactions occurred most often with daily dosing compared to other dosing regimes.

Adverse reactions reported with greater than 2% frequency in the two field studies.

Adverse Reaction*	Number (Percent) of Cases n= 205
Vomiting/Retching/Regurgitation	72 (35.1%)
Weight Loss	42 (20.5%)
Diarrhea	31 (15.1%)
Anorexia/Decreased Appetite	29 (14.1%)
Lethargy/Malaise	28 (13.6%)
Hypersalivation	23 (11.2%)
Behavioral Disorder (hiding, hyperactivity, aggression)	18 (8.8%)
Ocular Discharge/Epiphora/Conjunctivitis	14 (6.8%)
Sneezing/Rhinitis	11 (5.4%)
Gingivitis/Gingival Hyperplasia	9 (4.4%)
Polydipsia	6 (2.9%)

*Cats may have experienced more than one type or occurrence of a reaction during the studies.

The following adverse reactions were reported in less than or equal to 2% of cats treated with cyclosporine in the two field studies: bacterial dermatitis, hepatic lipidosis and jaundice, gastrointestinal small cell lymphoma, constipation, cough, toxoplasmosis, muscle wasting, muscle tremors, ataxia, convulsion, polyuria, urinary tract infection, inappropriate urination or defection, seborrhea, worsening otitis externa, papilloma, leukotrichia (whitening of hair) and excessive hair growth, anemia, lymphopenia, worsening monocytosis, worsening neutrophilia, hyperglobulinemia, increased serum creatinine and urea nitrogen, and increased alanine aminotransferase.

Contact Information:
To report suspected adverse events, for technical assistance or to obtain a copy of the safety data sheet (SDS), contact Ceva Animal Health at 1-800-999-0297 or www.ceva.us. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS, or www.fda.gov/reportanimalae.

Information for Cat Owners:
Owners should be advised to discontinue MODULIS® for Cats and contact their veterinarian in case of signs of serious illness and/or persistent, progressive weight loss. Owners should be informed of the risks of increased susceptibility to infection and the development of neoplasia, and they should be provided advice on how to avoid exposure of their cat to *Toxoplasma gondii* infection.

Clinical Pharmacology:
Cyclosporine is an immunosuppressive agent that has been shown to work via suppression of T-helper and T-suppressor cells and inhibition of interleukin-2. It does not depress hematopoiesis or the function of phagocytic cells. Cyclosporine is not a corticosteroid or antihistamine.

Following an intravenous dose of 2 mg/kg in a 24-hour fasted state, clearance of cyclosporine A in cats was 0.199 L/kg x h and half life was ~24 hours. After oral administration, the terminal elimination half life has been estimated to be as short as 6.8 to longer than 40 hours in some normal healthy cats.

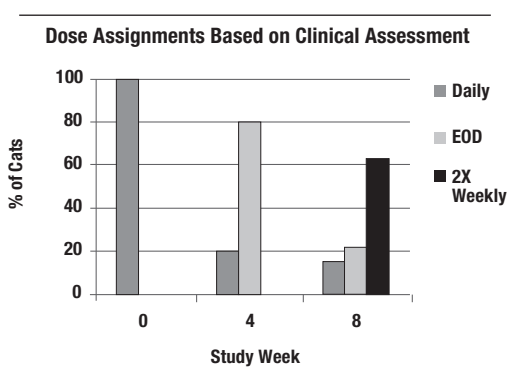
The bioavailability of cyclosporine is highly variable both within and between cats. A pharmacokinetic study showed no consistent difference in the mean extent of drug absorption when administered orally to fed or fasted cats or mixed in with food.

Blood levels of cyclosporine in field studies were highly variable, even among cats with similar clinical response, suggesting no generalizable correlations can be made between cats with regard to blood cyclosporine levels and clinical response (effectiveness and safety). Nevertheless, individual differences in the relationship between drug exposure and clinical response may exist. Therefore, to minimize individual fluctuations in drug absorption, MODULIS® for Cats should be administered on a consistent schedule with regard to meals and time of day.

Effectiveness:
A masked, controlled field study was conducted at 24 sites from various geographic locations in the United States and Canada. In this study, 217 client-owned cats with clinical signs consistent with allergic dermatitis (miliary dermatitis, excoriations including facial or neck, self-induced alopecia and eosinophilic plaques) along with non-seasonal localized or generalized pruritus, were randomly assigned in a 2:1 ratio and received either cyclosporine or a control solution (the excipients of Cyclosporine Oral Solution, USP without the cyclosporine). Owners administered treatment in a small amount of food or directly in the cat's mouth just after feeding once daily for up to 6 weeks. No additional therapy with antihistamines, corticosteroids or medicated shampoos was permitted.

Effectiveness was evaluated in 181 cats. Cats in the cyclosporine treatment group had a 65.1% reduction in mean total lesion score, compared to cats in the control treatment group, which had a 9.2% reduction in mean total lesion score. The percent of cats identified as treatment success by the Owner was 78.6% in the cyclosporine group compared to 26.2% in the control group. Compared to the control group, the cyclosporine group had improved mean ratings for Investigator assessment of overall improvement, Owner and Investigator assessment of pruritus, and number of body regions with lesions.

After drop-out from or completion of the masked 6-week field study, 191 cats were enrolled in a 12-week open-labeled field study to evaluate dose tapering of cyclosporine. The graph below shows the dose assignments for each 4-week dosing period. At study entry, all cats were assigned daily doses. At Week 4, cats were assigned daily or every other day (EOD) dosing, based on clinical improvement. At Week 8, cats were assigned daily, EOD, or twice weekly (2X Weekly) dosing for the final month of the study. Cats with poor responses exited the study at Weeks 4 and 8. At study exit at Week 12, 62.9%, 21.6%, and 15.5% of the remaining 97 evaluable cats were on twice weekly, EOD, and daily dosage regimens, respectively.



Cyclosporine was used in conjunction with various medications including a macrocyclic lactone and other antiparasitic agents, systemic antimicrobials, and topical skin and otic cleansers and antimicrobials.

Animal Safety:
In a 6-month safety study, forty (20 male and 20 female) 6-month old cats were randomized into 5 treatment groups and administered 0, 8, 16, 24 or 40 mg/kg/day cyclosporine (0, 1, 2, 3 or 5X the maximum therapeutic dose). An intermittent interventricular conduction disturbance was noted on electrocardiogram in one 3X and one 5X treatment group cat following 6 months of dosing. A 5X cat was euthanized after two weeks of treatment following a rapidly-declining clinical condition including recumbency, inappetance, dehydration, and decreased body weight. A post-mortem examination showed a healing rib fracture and bone marrow hypocellularity characterized by a moderate reduction in the number of bone marrow cells from multiple lineages. Hematology parameters drawn prior to euthanasia for this cat did not reveal abnormalities indicative of bone marrow hypocellularity. A 5X female cat presented with abdominal fibroadenomatous nodules during the study. Lymphoma of the kidneys and a mesenteric lymph node were present on necropsy in one 5X male, which is likely related to the immunosuppressive effects of cyclosporine treatment. Activated partial thromboplastin time (APTT) was prolonged in treated cats when compared to control cats.

A safety study was conducted to evaluate the effect of cyclosporine on the development of vaccine titers following vaccination in cats. Thirty-two cats (16 males and 16 females) were randomized into two treatment groups. Group 1 cats served as the control group and were sham dosed. Group 2 cats were administered cyclosporine at a dose of 24 mg/kg (3X the maximum therapeutic dose) orally once daily for 56 days. All cats were approximately 7 months of age at the start of the study and previously vaccinated against feline calici virus (FCV), feline panleukopenia virus (FPV), feline leukemia virus (FeLV), feline herpes virus-1 (FHV-1) and rabies with the final pre-treatment vaccines administered 16 weeks prior to treatment with cyclosporine. Cats were naïve to the feline immunodeficiency virus (FIV) vaccine, which was administered after 28 days on cyclosporine. After booster vaccinations on Day 28, titers for FCV, FPV, FeLV, FHV-1 and rabies were decreased in cyclosporine treated cats compared to control cats, but these titers remained adequate in both treatment groups. In contrast, cats on high-dose cyclosporine failed to develop titers to the novel vaccine (FIV). An increase in incidence and frequency of diarrhea, vomiting, and salivation were noted in Group 2 cats. One female cat treated with cyclosporine was observed to be in estrus during the study compared to 5 of the female control cats. One cat treated with cyclosporine was noted as having a slow or absent startle reflex, displayed ataxia, had small lymph nodes, thin body condition, and gas and fluid filled loops of intestine. Lymphocyte counts were lower in treated cats when compared to control. APTT was prolonged in treated cats when compared to control cats. Cholesterol, glucose, total protein, blood urea nitrogen, and creatinine values were elevated in cyclosporine treated cats with values just above the normal reference range. Glucosuria was noted in three treated animals that also had hyperglycemia.

A safety study was conducted to evaluate the effects of cyclosporine on the clinical course of *Toxoplasma gondii*. Thirty domestic short-haired cats (15 males and 15 females) ranging in age from 1-2 years were randomized into three treatment groups. Group 1 cats served as the control group and were administered placebo. Group 2 cats were administered placebo for 84 days followed by treatment with cyclosporine for 42 days. Group 3 cats were treated with cyclosporine for 126 days. Cyclosporine was administered at a target dose of 7.5 mg/kg orally once daily. All cats were infected with *T. gondii* cysts on Study Day 42.

One cat was found dead and another was euthanized (both in Group 3) within six weeks following infection due to complications related to toxoplasmosis. Clinical signs typical of *T. gondii* infection, including bloody feces, lethargy, and vomiting/regurgitation, were also seen in

most of the remaining cats, but resolved within six weeks following infection. Decreases in body weight and food consumption were seen in some cats from each group, but these changes were reversible as the animals recovered from clinical toxoplasmosis.

APTT was prolonged in Group 2 and 3 cats receiving cyclosporine when compared to Group 1 cats. Cholesterol, glucose and total protein/globulin values were elevated in cyclosporine treated cats. Ocular changes consistent with toxoplasmosis were seen in one to two cats in each group. The oocyst shedding period and number of oocysts shed were increased in Group 1 and 2 cats compared to Group 3 cats. All inoculated cats developed *T. gondii* IgG antibodies; IgM titers were detected in only 3 cats. Post-mortem examinations revealed mild to moderate inflammation in the central nervous system and pulmonary tissues, with the highest incidence and severity generally following this trend: Group 3 > Group 2 > Group 1. Lesions were consistent with *T. gondii* infection and were more prevalent in males than females. *T. gondii* organisms were only detected histopathologically in the tissues of the two Group 3 cats that died of toxoplasmosis.

Storage Information:
MODULIS® for Cats should only be dispensed in the original container and stored at controlled room temperature between 59 and 77°F (15-25°C). Modulis® for Cats does not require refrigeration. Once opened, use contents within 9 weeks for the 4.7 mL container and 16 weeks for the 15 and 30 mL containers.

How Supplied:
MODULIS® for Cats (cyclosporine oral solution) USP MODIFIED is supplied in glass amber bottles of 4.7, 15, and 30 mL at 100 mg/mL. A dispensing system is included (See **Instructions for Assembling the Dispensing System and Preparing a Dose of MODULIS® for Cats**).

Manufactured for:
Ceva Animal Health, LLC.
Lenexa, KS 66215

Approved by FDA under ANADA # 200-744

MODULIS® is a registered trademark of Ceva Santé Animale S.A.

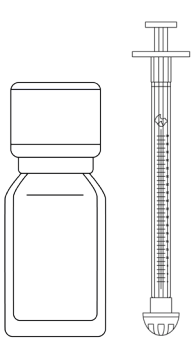
REV:10/23

F44010N 08-A1-v1

Made in Germany

Instructions for Assembling the Dispensing System and Preparing a Dose of MODULIS® for Cats (cyclosporine oral solution) USP MODIFIED

Assembling the Dispensing System



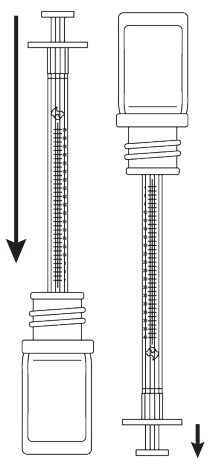
The dispensing system consists of 2 parts:

1. A bottle containing the medicine, fitted with a pre-inserted plastic adapter and a screw cap to close the bottle after use. Do not remove the adapter from the neck of the bottle. It must remain in place for the duration of use.

2. An oral dosing syringe that fits into the top of the plastic adapter to withdraw the prescribed dose of the medicine from the bottle. The oral dosing syringe comes with a plastic cap. Save the plastic cap to protect the oral dosing syringe during storage between each use.

Note: To prepare a dose, carefully follow the instructions for **Preparing a Dose of Medicine.**

Preparing a Dose of Medicine.



1. Push and turn the child-resistant screw cap to open the bottle. **Note:** Always close the bottle with the child-resistant screw cap after use.

2. Remove the plastic cap and check that the plunger of the oral dosing syringe is pushed all the way down.

3. Keep the bottle upright and insert the oral dosing syringe firmly into the plastic adapter.

4. Invert the bottle/syringe, and slowly pull the plunger down so that the oral dosing syringe fills with the medicine.

5. **Expel any large bubbles by pushing and pulling the plunger a few times. The presence of a few tiny bubbles is not important for dose accuracy.**

6. Withdraw the dose of medicine prescribed by your veterinarian. The scale on the oral dosing syringe corresponds to the cat's body weight.

Note: If the prescribed dose is more than the maximum volume marked on the oral dosing syringe, you will need to reload the syringe to withdraw the full dose.

7. Return the bottle/syringe to the upright position, and gently remove the oral dosing syringe from the plastic adapter.

You can now place the oral dosing syringe over a small amount of food or introduce the syringe in the mouth of your cat and push the medicine out of the syringe.

See Information for Cat Owners for complete administration instructions.

Do not rinse or clean the oral dosing syringe between uses. Replace the plastic cap to store the oral dosing syringe between each use.

MODULIS® for Cats should only be dispensed in the original container and stored between 59 and 77°F (15 - 25°C). MODULIS® for Cats does not require refrigeration. Once opened, use contents within 9 weeks for the 4.7 mL container and 16 weeks for the 15, and 30 mL containers.

Close the bottle with the child-resistant screw cap after use.

Keep out of reach of children!

Always close the bottle with the child-resistant screw cap after use. To provide a child-resistant closure, push down on the child-resistant screw cap as you turn it.

MODULIS® for Cats (cyclosporine oral solution) USP MODIFIED

Information for Cat Owners

MODULIS® for Cats is indicated for the control of feline allergic dermatitis. Cats with allergic dermatitis scratch, lick and chew their skin which can cause red, raised crusty bumps, open sores and/or hair loss.

Allergic dermatitis is a common skin disease in cats and is caused by allergens such as house dust mites or pollens which stimulate an exaggerated immune response. The disease is chronic, recurrent, and requires lifelong management.

This summary contains important information about MODULIS® for Cats. You should read this information before starting your cat on MODULIS® for Cats. This sheet is provided only as a summary and does not take the place of instructions from your veterinarian. Talk to your veterinarian if you do not understand any of this information or you want to know more about MODULIS® for Cats.

What is MODULIS® for Cats?
MODULIS® for Cats is an oral solution of cyclosporine that lowers the immune response. MODULIS® for Cats selectively acts on the immune cells involved in the allergic reaction. MODULIS® for Cats reduces the inflammation and itching associated with allergic dermatitis.

What kind of results can I expect when my cat takes MODULIS® for Cats for the control of feline allergic dermatitis?
MODULIS® for Cats should be given daily until improvement is seen. This will generally be the case within 4-6 weeks. You should contact your veterinarian if you are not satisfied with your cat's response. Once the signs of allergic dermatitis are satisfactorily controlled, your veterinarian may reduce the frequency of administration of the product. Dose adjustment should only be carried out in consultation with your veterinarian.
Your veterinarian will perform a clinical assessment at regular intervals and adjust the frequency of administration up or down according to the clinical response obtained.

What cats should not take MODULIS® for Cats?
Your cat should not be given MODULIS® for Cats if s/he:
- Has a history of cancer or may possibly have cancer currently
- Has been diagnosed with feline leukemia virus (FeLV) or feline immunodeficiency virus (FIV)
- Is hypersensitive to cyclosporine

What to discuss with your veterinarian before giving MODULIS® for Cats to your cat.
Tell your veterinarian about:
- Any digestive upset (vomiting or diarrhea) your cat has had
- Any history of lack of appetite and/or weight loss your cat has had
- Any serious disease or health conditions your cat has had
- Any allergies that your cat has now or has had
- All medications that you are giving your cat or plan to give your cat, including those you can get without prescription (over the counter) and any dietary supplements
- If you plan to breed your cat, or if your cat is pregnant or nursing

Talk to your veterinarian about:
- What tests might be done before MODULIS® for Cats is prescribed
- The potential side effects your cat may experience while taking MODULIS® for Cats
- How often your cat may need to be examined by your veterinarian
- The risks and benefits of using MODULIS® for Cats

What are the possible side effects that may occur in my cat during therapy with MODULIS® for Cats?
MODULIS® for Cats, like all other drugs, may cause some side effects in individual cats. These are normally mild, but serious side effects have been reported in cats taking MODULIS® for Cats. Serious side effects can, in rare situations, result in death. It is important to stop the medication and contact your veterinarian immediately if you think your cat may have a medical problem or side effect while on MODULIS® for Cats. To report adverse effects, access medical information, or obtain additional product information call 1-800-999-0297.

In clinical studies, the most commonly reported side effect was vomiting. In most cases, the vomiting stopped with continued use. Weight loss, diarrhea, decreased appetite, lethargy, and drooling were the next most frequent side effects observed.

Persistent, progressive weight loss may be associated with more serious side effects. You should monitor your cat's appetite and body weight. If you think that your cat is losing weight, you should contact your veterinarian.

MODULIS® for Cats may increase susceptibility to infection and to the development of tumors.

MODULIS® for Cats should only be given to cats.

People should not take MODULIS® for Cats. Keep MODULIS® for Cats and all medication out of reach of children. Call your physician immediately if you accidentally swallow MODULIS® for Cats.

How to give MODULIS® for Cats to your cat.

MODULIS® for Cats should be given according to your veterinarian's instructions. Your veterinarian will tell you what amount of MODULIS® for Cats is right for your cat. MODULIS® for Cats can be given either mixed with food or directly into the cat's mouth. If given with food, the solution should be mixed with a small amount of food, preferably after a sufficient period of fasting to ensure your cat eats it completely. When given directly into the mouth, insert the oral dosing syringe into the cat's mouth and deliver the entire dose, just after feeding. Whenever possible, you should administer MODULIS® for Cats on a consistent schedule with regard to meals and time of day. Do not change the way you give MODULIS® for Cats to your cat without first speaking with your veterinarian. 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. **Do not rinse or clean the oral dosing syringe between uses.**

Advice on Correct Administration.
See **Instructions for Assembling the Dispensing System and Preparing a Dose of MODULIS® for Cats.**

How to Store MODULIS® for Cats.
MODULIS® for Cats should be stored in the original container at controlled room temperature between 59 and 77°F (15-25°C). Modulis® for Cats does not require refrigeration. Once opened, use contents within 9 weeks for the 4.7 mL container and 16 weeks for the 15 and 30 mL containers.

Special precautions to be taken when administering MODULIS® for Cats. Do not eat, drink, smoke, or use smokeless tobacco while handling MODULIS® for Cats.
Wash hands after administration.
In case of accidental ingestion, seek medical advice immediately and show the package insert or the label to the physician.
People with known hypersensitivity to cyclosporine should avoid contact with MODULIS® for Cats.

Can MODULIS® for Cats be given with other medications?
MODULIS® for Cats should not be given with other drugs that may lower the immune response.
Cylclosporine has been safely used in conjunction with other common medications. However, interactions with certain medications are possible. Therefore, always tell your veterinarian about all medications that you have given your cat in the past and all medications that you are planning to give with MODULIS® for Cats.

What can I do in case my cat gets more than the prescribed amount of MODULIS® for Cats?
Contact your veterinarian immediately if your cat gets more than the prescribed amount of MODULIS® for Cats.

What else should I know about MODULIS® for Cats?
Toxoplasma gondii is a protozoal parasite that cats can become infected with from eating raw meat. Infection may lead to serious illness (clinical toxoplasmosis). Cats that have not been exposed to *Toxoplasma gondii* may be at risk of developing clinical toxoplasmosis if they become infected while under treatment with MODULIS® for Cats, which can be fatal. To avoid infection keep your cat indoors, do not feed raw meat, and do not allow your cat to hunt.

If your cat becomes seriously ill, consult your veterinarian who will recommend the appropriate treatment.

This sheet provides a summary of information about MODULIS® for Cats. If you have any questions or concerns about MODULIS® for Cats or allergic dermatitis in cats, talk to your veterinarian.

As with all prescribed medications, MODULIS® for Cats should only be given to the cat for which it was prescribed. It should be given to your cat only for the condition for which it was prescribed, at the prescribed dose, and as directed by your veterinarian.