ATOPICA for Cats
(cyclosporine oral solution) USP MODIFIED
100 mg/mL
CA4900                  PA100075AMX                      W1a

Instructions for Preparing a Dose of Medicine

ATOPICA for Cats is a systemic immunosuppressant that may increase the susceptibility to infection and the development of neoplasia. One to two cats in each group. The oocyst shedding period and number of oocysts shed were increased in Group 1 and 2 cats. Decreases in body weight and food consumption were seen in some cats within six weeks following infection due to complications related to toxoplasmosis. Clinical signs typical of T. gondii infection keep your cat indoors, do not feed raw meat, and do not allow your cat to hunt.

Toxoplasmosis is a disease caused by a protozoan parasite, Toxoplasma gondii, which can infect cats and other animals, including humans. Symptoms include fever, lymph node enlargement, and sometimes severe neurological problems. Treatment typically involves supportive care and may include medication to combat the infection. Owners should be aware of the potential for transmission to their cat and采取相应的预防措施，以避免疾病的发生。
A safety study was conducted to evaluate the effect of ATOPICA for Cats on the development of vaccine titers following vaccination in cats. Thirty-six cats (16 males and 15 females) were randomized into two treatment groups. Group 1 cats served as the control group and were sham dosed. Group 2 cats were administered ATOPICA for Cats 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 herpesvirus-1 (FHV-1) and rabies with the pre-fight treatment-vaccines administered 16 weeks prior to treatment with cyclosporine. Cats were naive to the feline immunodeficiency virus (FIV) vaccine, which was administered 24 days after on cyclosporine. Booster vaccinations on Day 28, titers for FCV, FPV, FHV-1, and rabies were performed on Groups 2 cats. One week post-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 compared to control. JPT was prolonged in treated cats when compared to control cats. Cholesterol, glucose, total protein, and urea nitrogen concentrations were elevated in cyclosporine treated cats compared with values above the normal reference range. Glucocorticosteroids was noted in three treated animals that also had hypoglycemia.

A safety study was conducted to evaluate the effects of ATOPICA for Cats 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 cyclosporine for 48 days followed by treatment with ATOPICA for Cats for 42 days. Group 3 cats were treated with ATOPICA for Cats for 126 days. ATOPICA for Cats was administered at a target dose of 1.5 mg/kg orally once daily. All cats were infected with a virulent T. gondii cysts at 18 weeks of age and whether they were euthanized (both euthanized) 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 of the cats from each group, but these changes were reversible as the animals recovered from clinical toxoplasmosis. JPT 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. Occasional changes consistent with toxoplasmosis were seen in one to two cats in each group. The ocular 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:
ATOPICA for Cats should only be dispensed in the original container and stored at controlled room temperature between 59 and 77°F (15-25°C). Once opened, use contents within two months for the 5 mL container and 11 weeks for the 17 mL container.

How Supplied:
ATOPICA for Cats (cyclosporine oral solution) USP MODIFIED is supplied in glass amber bottles of 5 mL and 17 mL at 100 mg/mL. A dispensing system is included (See Instructions for Assembling the Dispensing System and Preparing a Dose of ATOPICA for Cats).

Manufactured for:
Elanco Animal Health, Inc. 1 Animal Health Blvd. Greenfield, IN 46140, USA

NADA 141-329, Approved by FDA

Dosage and Administration:
ATOPICA 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 in a cat is caused by allergies 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 ATOPICA for Cats. You should read this information before starting your cat on ATOPICA for Cats. This sheet may be 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 ATOPICA for Cats.

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

What kind of results can I expect when my cat takes ATOPICA for Cats for the control of feline allergic dermatitis?
ATOPICA 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 seen to be completely 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 ATOPICA for Cats?
Your cat should not be given ATOPICA for Cats if:

• 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 can you discuss with your veterinarian before giving ATOPICA 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 your cat’s body weight 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 ATOPICA for Cats is prescribed
• The potential side effects your cat may experience while taking ATOPICA for Cats
• How often your cat may need to be examined by your veterinarian
• The risks and benefits of using ATOPICA for Cats

What are the possible side effects that may occur in my cat during therapy with ATOPICA for Cats?
ATOPICA 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 ATOPICA for Cats. Serious side effects can, in rare cases, 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 ATOPICA for Cats. To report adverse events, access medical information, or obtain additional product information, call 1-888-545-5973.

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’s body weight is low, you should contact your veterinarian.

ATOPICA for Cats may increase susceptibility to infection and to the development of tumors. ATOPICA for Cats should only be given to cats whose body temperature is lower than normal.

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

How to give ATOPICA for Cats to your cat.

ATOPICA for Cats should be given according to your veterinarian’s instructions. Your veterinarian will tell you what amount of ATOPICA for Cats is right for your cat. ATOPICA for Cats can be given either mixed with food or directly into the cat’s mouth and swallowed. The only limitation should be mixed with a small amount of food, preferably at a feeding time. If your cat is not interested in eating, you must mix the dose with food or use a syringe to administer the dose.

You may need to give ATOPICA for Cats orally once daily, twice daily, 2-3 times a day, or even more frequently. 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.

Advise on Correct Administration:

Assembling the Dispensing System

The dispensing system consists of 4 parts:

1. A bottle containing the medicine, with rubber stopper and a screw cap to close the bottle
2. A plastic adapter with dip tube that you will push into the neck of the bottle. The adapter must always remain in the bottle after first use.
3. An oral dosing syringe that fits into the top of the plastic adapter to withdraw the prescribed dose of medicine from the bottle.
4. A plastic syringe with the plastic adapter and oral dosing syringe. Save the plastic valve to store the oral dosing syringe between use each use.

Fitting the Plastic Adapter into the New Bottle of Medicine

1. Remove the valve from the screw cap.
2. Hold the open bottle upright on a table and push the plastic adapter firmly into the neck of the bottle.
3. Push the screw cap down on the child-resistant screw cap as you turn it.

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. Push firmly against the bottle to push all the way down.
3. Keep the bottle upright and insert the oral dosing syringe firmly into the plastic adapter.
4. Slightly pull the plunger up so that the oral dosing syringe fills with the medicine.
5. Keep the bottle upright by holding the screw cap with your thumb or index finger.
6. The presence of a few tiny bubbles is not important for dosing accuracy.
7. Withdraw the dose of medicine prescribed by your veterinarian. The scale on the oral dosing syringe is measured in milligrams, 1 mL = 1,000 mg.
8. If the prescribed dose is more than the maximum volume marked on the oral dosing syringe, you will need to reball the syringe to withdraw the full dose.
9. Remove the oral dosing syringe by gently twisting it out of the plastic adapter.
10. 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.
11. Do not rinse or clean the oral dosing syringe between uses. Store the oral dosing syringe in the plastic tube between each use.

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.