ATOPICA FOR CATS- cyclosporine solution
Elanco US Inc.

Atopica™ for Cats
(cyclosporine oral solution) USP MODIFIED
100 mg/mL

Caution:

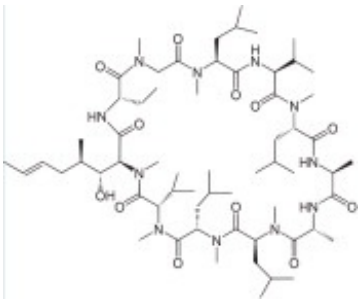
Federal Law restricts this drug to use by or on the order of a licensed veterinarian.

Description:

ATOPICA 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 ATOPICA 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-ananyl-N-methyl-L-leucyl-N-methyl-L-leucyl-N-methyl-L-valyl].

The structural formula is:



Indication:

ATOPICA 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 ATOPICA for Cats and the Information for Cat Owners with prescription.

The initial dose of ATOPICA 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 ATOPICA for Cats may be tapered by decreasing the frequency of dosing to every other day or twice weekly to maintain the desired therapeutic effect. ATOPICA for Cats should be administered directly on a small amount of food or orally just after feeding. Whenever possible, ATOPICA 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 ATOPICA 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:

ATOPICA 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 ATOPICA for Cats 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 ATOPICA for Cats:

Do not eat, drink, smoke, or use smokeless tobacco while handling ATOPICA 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 ATOPICA for Cats.

Precautions:

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

ATOPICA 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. ATOPICA 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.

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

ATOPICA for Cats should be used with caution with drugs that affect the P-450 enzyme system. Simultaneous administration of ATOPICA 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 ATOPICA 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 ATOPICA for Cats 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 ATOPICA for Cats 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 ATOPICA for Cats 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 drug events or for technical assistance, contact Elanco US Inc. at 1-888-545-5973. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae

Information for Cat Owners:

Owners should be advised to discontinue ATOPICA 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 hematopoesis or the function of phagocytic cells. ATOPICA for Cats 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 ATOPICA for Cats 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, ATOPICA for Cats should be administered on a consistent schedule with regard to meals and time of day.

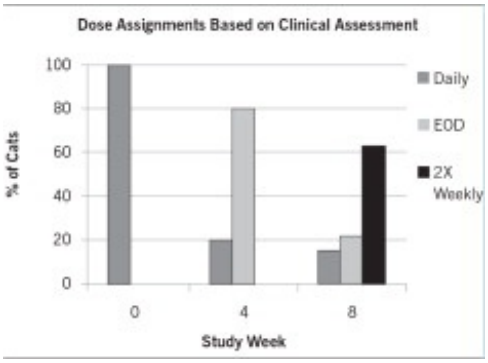
Effectiveness:

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 ATOPICA for Cats or a control solution (the excipients of ATOPICA for Cats 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 ATOPICA for Cats 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 ATOPICA for Cats group compared to 26.2% in the control group. Compared to the control group, the ATOPICA for Cats 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 ATOPICA for Cats. 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.



ATOPICA for Cats 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 ATOPICA for Cats (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 ATOPICA for Cats 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 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 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 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 placebo for 84 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 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:

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 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 US Inc. Indianapolis, IN 46221, USA
Product of Ireland
Product of India
Approved by FDA under NADA # 141-329
Revision Date: November 2025
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Instructions for Assembling the Dispensing System and Preparing a Dose of ATOPICA™ for Cats (cyclosporine oral solution) USP MODIFIED

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 after use.
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 vial containing the plastic adapter and oral dosing syringe. Save the plastic vial to store the oral dosing syringe between each use.

Fitting the Plastic Adapter into the New Bottle of Medicine

- Remove and save the screw cap.

- Remove and dispose of the rubber stopper.
- Hold the open bottle upright on a table and push the plastic adapter **firmly** into the neck of the bottle as far as you can, then close the bottle with the screw cap.
- To provide a child-resistant closure, push 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. 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. Slowly pull the plunger up 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 dosing 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. Remove the oral dosing syringe by gently twisting it out of 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. Store the oral dosing syringe in the plastic tube between each use.

ATOPICA for Cats should be stored in the original container at room temperature between 59 and 77°F. Once opened, use contents within two months for the 5 mL container and 11 weeks for the 17 mL container.

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.

ATOPICA™ for Cats (cyclosporine oral solution) USP MODIFIED

Information for Cat Owners

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 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 ATOPICA for Cats. You should read this information before starting your cat on ATOPICA 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 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 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 ATOPICA for Cats?

Your cat should not be given ATOPICA 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 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 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 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 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 ATOPICA for Cats. To report adverse effects, 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 is losing weight, 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.

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. 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 ATOPICA for Cats on a consistent schedule with regard to meals and time of day. Do not change the way you give ATOPICA 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 ATOPICA for Cats.** If your veterinarian has already assembled the dispensing system, skip the instructions for assembling the dispensing system and follow the instructions for preparing a dose of medicine.

How to Store ATOPICA for Cats.

ATOPICA for Cats should be stored in the original container at room temperature between 59 and 77°F. Once opened, use contents within two months for the 5 mL container and 11 weeks for the 17 mL container.

Special precautions to be taken when administering ATOPICA for Cats.

Do not eat, drink, smoke, or use smokeless tobacco while handling ATOPICA 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 ATOPICA for Cats.

Can ATOPICA for Cats be given with other medications?

ATOPICA for Cats should not be given with other drugs that may lower the immune response.

ATOPICA for Cats 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 ATOPICA for Cats.

What can I do in case my cat gets more than the prescribed amount of ATOPICA for Cats?

Contact your veterinarian immediately if your cat gets more than the prescribed amount of ATOPICA for Cats.

What else should I know about ATOPICA 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 ATOPICA 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 ATOPICA for Cats. If you have any questions or concerns about ATOPICA for Cats or allergic dermatitis in cats, talk to your veterinarian.

As with all prescribed medications, ATOPICA 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.

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Elanco™

Principal Display Panel - 5 mL Carton Label

Atopica™ for Cats

(cyclosporine oral solution) USP MODIFIED

100 mg/mL

Caution:

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

For oral use in cats only

Net contents:

1 vial containing 5 mL, 100 mg/mL cyclosporine
A dispensing system

Approved by FDA under NADA # 141-329

5 mL

Elanco™

Atopica™ for Cats
(cyclosporine oral solution) USP MODIFIED
100 mg/mL

310032
SH231736A

Atopica™ for Cats

(cyclosporine oral solution) USP MODIFIED 100 mg/mL

Indication:
ATOPICA 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.

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.

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

Dosage and Administration:
Read package insert before using drug.

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.

5mL

Elanco

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

For oral use in cats only

Net contents:
1 vial containing 5 mL, 100 mg/mL cyclosporine
A dispensing system

Approved by FDA under NADA # 141-329

Manufactured for:
Elanco US Inc.
Indianapolis, IN 46221, USA
Product of India

5mL 5mL

Elanco

Exp:
Lot:

Principal Display Panel - 17 mL Carton Label

Atopica™ for Cats

(cyclosporine oral solution) USP MODIFIED

100 mg/mL

Caution:

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

For oral use in cats only

Net contents:

1 vial containing 17 mL, 100 mg/mL cyclosporine
A dispensing system

Approved by FDA under NADA # 141-329

17 mL

Elanco™

ATOPICA FOR CATS

cyclosporine solution

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:58198-9725
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**

cyclosporine (UNII: 83HN0GTJ6D) (cyclosporine - UNII:83HN0GTJ6D)	cyclosporine	100 mg in 1 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58198-9725-1	1 in 1 CARTON		
1		5 mL in 1 BOTTLE, GLASS		
2	NDC:58198-9725-2	1 in 1 CARTON		
2		17 mL in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA141329	11/01/2015	

Labeler - Elanco US Inc. (966985624)

Revised: 7/2026 Elanco US Inc.