PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard Box}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atopica 100 mg/ml oral solution

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

ciclosporin 100 mg/ml

Excipients: all-rac-α-tocopherol (E-307) 1.05 mg, ethanol, anhydrous (E-1510) 94.70 mg and propylene glycol (E-1520) 94.70 mg.

3. PACKAGE SIZE

5 ml
17 ml
50 ml

4. TARGET SPECIES

Cats

Dogs (weighing more than 2 kg)

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Not applicable

8. EXPIRY DATE

Exp. {mm/yyyy}

5 ml and 17 ml: Once opened use within 70 days.

50 ml: Once opened use within 84 days.

Once opened, use by:

9. SPECIAL STORAGE PRECAUTIONS

Store between 15°C and 30°C but preferably not below 20°C for more than one month.

Keep the bottle in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

14. MARKETING AUTHORISATION NUMBER

Vm 00879/5018

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read the package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V: To be supplied only on veterinary prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Glass bottle (5 ml, 17 ml and 50 ml)}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atopica

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

ciclosporin 100 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 ml and 17 ml: Once opened use within 70 days.

50 ml: Once opened use within 84 days.

6. ROUTE(S) OF ADMINISTRATION

7. WITHDRAWAL PERIOD

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atopica 100 mg/ml oral solution for cats and dogs

2. COMPOSITION

Each ml contains:
Active substance: ciclosporin 100 mg

Excipients: all-rac-α-tocopherol (E-307) 1.05 mg, ethanol, anhydrous (E-1510) 94.70 mg and propylene glycol (E-1520) 94.70 mg.

Clear, yellow to brownish liquid.

3. TARGET SPECIES

Cats

Dogs (weighing more than 2 kg).

4. INDICATIONS FOR USE

Symptomatic treatment of chronic allergic dermatitis in cats.
Treatment of chronic manifestations of atopic dermatitis in dogs.

Allergic dermatitis and atopic dermatitis are common skin diseases in cats and dogs, respectively. They are caused by allergens such as house dust mites or pollens which stimulate an exaggerated immune response. The diseases are chronic and recurrent. Ciclosporin selectively acts on the immune cells involved in the allergic reaction. Ciclosporin reduces the inflammation and itching associated with allergic dermatitis.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cats infected with FeLV or FIV.
Do not use in animals with a history of malignant disorders or progressive malignant disorders.
Do not vaccinate with a live vaccine during treatment or within a two-week interval before or after treatment.
Do not use in dogs less than six months of age or less than 2 kg in weight.

6. SPECIAL WARNING(S)

Special precautions for safe use in the target species:
Clinical signs of atopic and allergic dermatitis such as itching and skin inflammation are not specific for this disease. Other causes of dermatitis such as ectoparasitic infestations or food allergy should be evaluated and eliminated where possible by your veterinary surgeon. It is good practice to treat flea infestations before and during treatment of atopic and allergic dermatitis.

Your veterinary surgeon will carry out a complete clinical examination prior to treatment. Any infections should be properly treated before initiation of treatment. Infections occurring during treatment are not necessarily a reason for drug withdrawal, unless the infection is severe.

While ciclosporin does not induce tumours, it does inhibit T-lymphocytes and therefore treatment with ciclosporin may lead to an increased incidence of clinically apparent malignancy due to the decrease in antitumor immune response. The potentially increased risk of tumour progression must be weighed against the clinical benefit. If lymphadenopathy (enlargement of the lymph glands) is observed in cats and dogs being treated with ciclosporin, further clinical investigations are recommended and treatment discontinued if necessary.

Ciclosporin may cause elevated levels of blood glucose. The use of ciclosporin is not recommended in diabetic cats and dogs.

Particular attention must be paid to vaccination. Treatment with the product may result in decreased immune response to vaccination. It is recommended not to vaccinate with inactivated vaccines during treatment or within a two-week interval before or after administration of the product.

It is not recommended to use immunosuppressive agents concomitantly.
Closely monitor creatinine levels with severe renal insufficiency.

Cats:
Allergic dermatitis in cats can have various manifestations, including eosinophilic plaques, head and neck excoriation, symmetrical alopecia and/or miliary dermatitis.

The immune status of your cat to FeLV and FIV infections should be assessed before treatment.

Cats that are seronegative for *T. gondii* may be at risk of developing clinical toxoplasmosis if they become infected while under treatment.

In rare cases this can be fatal. Potential exposure of seronegative cats or cats suspected to be seronegative to *Toxoplasma* should therefore be minimised (e.g. keep your cat indoors, avoid raw meat or scavenging). Ciclosporin was shown to not increase *T. gondii* oocyte shedding in a controlled laboratory study. In cases of clinical toxoplasmosis or other serious systemic illness consult your veterinary surgeon. Treatment should be stopped and appropriate therapy initiated.

Clinical studies in cats have shown that decreased appetite and weight loss may occur during ciclosporin treatment. It is recommended that you monitor the of body weight of your cat. Significant reduction in body weight may result in hepatic lipidosis (excessive accumulation of fat in the liver). If persistent, progressive weight loss occurs during treatment it is recommended to discontinue treatment until the cause has been identified.

The efficacy and safety of ciclosporin has neither been assessed in cats less than 6 months of age nor weighing less than 2.3 kg.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Accidental ingestion of this product may lead to nausea and/or vomiting. To avoid accidental ingestion, the product must be used and kept out of reach of children. Do not leave unattended filled syringe in the presence of children. Any uneaten medicated cat food must be disposed of immediately and the bowl washed thoroughly. In case of accidental ingestion, particularly by a child, seek medical advice immediately and show the package leaflet or the label to the physician.
Ciclosporin can trigger hypersensitivity (allergic) reactions. People with known hypersensitivity to ciclosporin should avoid contact with the veterinary medicinal product.
This veterinary medicinal product may cause irritation in case of eye contact. Avoid contact with eyes. In case of contact, rinse thoroughly with clean water.
Wash hands and exposed skin after administering the veterinary medicinal product.

Pregnancy and lactation:
The safety of the drug has neither been studied in male cats or dogs used for breeding nor in pregnant or lactating queens and bitches. In the absence of such studies, it is recommended to use the drug in breeding animals only upon a positive risk/benefit assessment by the veterinarian. Your veterinary surgeon should be advised if your animal is a breeding animal, so that a risk/benefit assessment can be made. The treatment of lactating queens and bitches is not recommended.

Interaction with other medicinal products and other forms of interaction:
Various substances are known to competitively inhibit or induce the enzymes involved in the metabolism of ciclosporin. In certain clinically justified cases, an adjustment of the dosage of the product may be required. The toxicity of some medications may be increased by administration with ciclosporin. Consult your veterinary surgeon prior to administering other products during therapy with this product.

Overdose:
The frequency and severity of adverse reactions are generally dose and time dependent. In case of signs of overdose, consult your veterinary surgeon immediately. There is no specific antidote and the animal should be treated symptomatically.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. ADVERSE EVENTS

Cats:

Very common (>1 animal / 10 animals treated):	Digestive tract disorders (such as Vomiting, Diarrhoea)[1]
Common (1 to 10 animals / 100 animals treated):	Lethargy[2], Anorexia[2], Weight loss[2]; Hypersalivation[2]; Lymphopenia[2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Leucopenia, Neutropenia, Thrombocytopenia; Diabetes mellitus.

[1]generally mild and transient and do not require the cessation of the treatment.
[2]generally resolve spontaneously after treatment is stopped or following a decrease in the dosing frequency
Side effects may be severe in individual animals.

Dogs:

Uncommon (1 to 10 animals / 1,000 animals treated):	Digestive tract disorders (such as Hypersalivation, Vomiting, Mucous stool, Loose stool, Diarrhoea)[1]
Rare (1 to 10 animals / 10,000 animals treated):	Lethargy[2], Anorexia[2]; Hyperactivity[2]; Gingival hyperplasia[2,3]; Skin reactions (such as Verruciform lesions, Hair change)[2] Pinnal reddening[2], Pinnal oedema[2]; Muscle weakness[2], Cramp[2].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Diabetes mellitus[4].

[1]generally mild and transient and do not require the cessation of the treatment
[2]generally resolve spontaneously after treatment is stopped
[3]mild to moderate
[4]mainly in West Highland White Terriers

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian.

You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For oral use. Before starting treatment, an evaluation of all alternative treatment options should be made. To ensure a correct dosage, body weight should be determined as accurately as possible.

Cats:
The recommended dose of ciclosporin is 7 mg/kg body weight (0.07 ml of oral solution per kg) and should initially be administered daily.
The veterinary medicinal product should be administered in accordance with the following table:

Bodyweight (kg)	Dose (ml)
2	0.14
3	0.21
4	0.28
5	0.35
6	0.42
7	0.49
8	0.56
9	0.63
10	0.70

The frequency of administration should subsequently be reduced depending on the response.

The product should initially be given daily until a satisfactory clinical improvement is seen (assessed by intensity of pruritus and lesion severity - excoriations, miliary dermatitis, eosinophilic plaques and/or self-induced alopecia). This will generally be the case within 4-8 weeks.

Once the signs of allergic dermatitis are satisfactorily controlled, the product can then be given every second day. In some cases where the signs of allergic dermatitis are controlled with every second day dosing, your veterinary surgeon can decide to give the product every 3 to 4 days. The lowest effective frequency of dosing should be used to maintain the remission of clinical signs.

The duration of treatment should be adjusted according to treatment response.
Treatment may be stopped when the clinical signs are controlled.

Upon recurrence of clinical signs, treatment should be resumed at daily dosing, and in certain cases repeated treatment courses may be required.

Dose adjustment should only be carried out in consultation with your veterinary surgeon. Your veterinary surgeon will perform a clinical assessment at regular intervals, adjust the frequency of administration up or down according to the clinical response obtained and review alternative treatment options.

The product can be given either mixed with food or directly into the 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 complete consumption by the cat. Should the cat not accept the product mixed with food, it should be given by inserting the syringe directly into the cat's mouth and delivering the entire dose. If the cat only partially consumes the product mixed with food, administration of the product with the syringe should be resumed only the next day.

The efficacy and tolerability of this product was demonstrated in clinical studies with a duration of 4.5 months.

Dogs:
The mean recommended daily dose of ciclosporin is 5 mg/kg body weight (0.05 ml of oral solution per kg). The veterinary medicinal product should be administered in accordance with the following table:

Bodyweight (kg)	Dose (ml)	Bodyweight (kg)	Dose (ml)	Bodyweight (kg)	Dose (ml)
		21	1.05	41	2.05
		22	1.10	42	2.10
3	0.15	23	1.15	43	2.15
4	0.20	24	1.20	44	2.20
5	0.25	25	1.25	45	2.25
6	0.30	26	1.30	46	2.30
7	0.35	27	1.35	47	2.35
8	0.40	28	1.40	48	2.40
9	0.45	29	1.45	49	2.45
10	0.50	30	1.50	50	2.50
11	0.55	31	1.55	51	2.55
12	0.60	32	1.60	52	2.60
13	0.65	33	1.65	53	2.65
14	0.70	34	1.70	54	2.70
15	0.75	35	1.75	55	2.75
16	0.80	36	1.80	56	2.80
17	0.85	37	1.85	57	2.85

Bodyweight (kg)	Dose (ml)	Bodyweight (kg)	Dose (ml)	Bodyweight (kg)	Dose (ml)
18	0.9	38	1.90	58	2.90
19	0.95	39	1.95	59	2.95
20	1.00	40	2.00	60	3.00

The veterinary medicinal product will initially be given daily until a satisfactory clinical improvement is seen. This will generally be the case within 4 weeks. If no response is obtained within the first 8 weeks, the treatment should be stopped.

Once the clinical signs of atopic dermatitis are satisfactorily controlled, the veterinary medicinal product can then be given every other day as a maintenance dose. In some cases where the clinical signs are controlled with every-other-day dosing, the veterinarian can decide to give the veterinary medicinal product every 3 to 4 days.
Adjunct treatment (e.g. medicated shampoos, fatty acids) may be considered before reducing the dosing interval.
Treatment may be stopped when the clinical signs are controlled. Upon recurrence of clinical signs, treatment should be resumed at daily dosing, and in certain cases repeated treatment courses may be required.

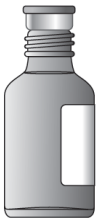
Dose adjustment should only be carried out in consultation with your veterinary surgeon. Your veterinary surgeon will perform a clinical assessment at regular intervals, adjust the frequency of administration up or down according to the clinical response obtained and review alternative treatment options.

The veterinary medicinal product should be given at least 2 hours before or after feeding. The product should be given by inserting the syringe directly into the dog’s mouth and delivering the entire dose.

9. ADVICE ON CORRECT ADMINISTRATION

Follow the instructions given by your veterinary surgeon. Take out the required volume of the medicinal product according to the body weight of your animal.

For the dosing process, carefully follow the handling/dispensing instructions as described below.

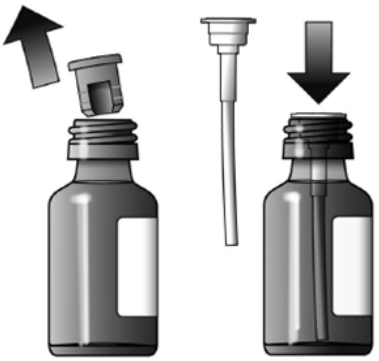
The Dispensing System The dispensing system consists of: 1. Bottle (5 ml or 17 ml): with rubber stopper and a child-resistant screw cap. Bottle (50 ml): with rubber stopper and aluminum tear-off cap. A separate child-resistant screw cap is included in the carton. 2. A plastic tube containing • A plastic adapter with dip tube and an oral dosing syringe	  
Prepare the Dispensing System Bottle (5 ml or 17 ml): Push and turn the child-resistant screw cap to open the bottle. Bottle (50 ml): Remove aluminum tear-off cap completely from the bottle.	

<u>All bottle sizes (5 ml, 17 ml and 50 ml):</u>

1. Remove and dispose rubber stopper.
2. Hold the open bottle upright on a table and push the plastic adapter firmly into the neck of the bottle as far as possible.
3. Close the bottle with the child-resistant screw cap.

The bottle is now prepared for dispense.

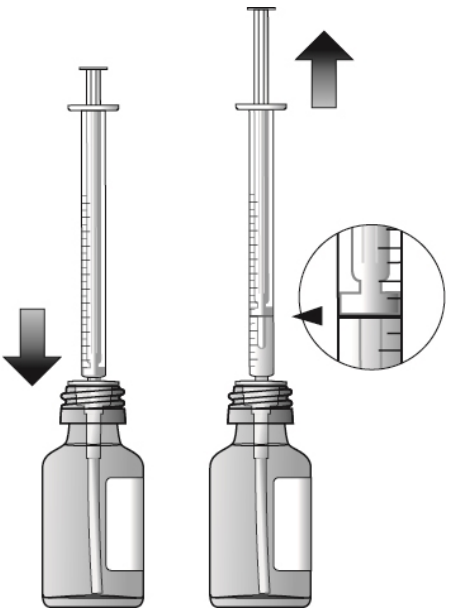
Note: Always close the bottle with the child-resistant screw cap after use. The adapter must always remain in the bottle after first use.



Preparing a Dose of Medicine

1. Push and turn the child-resistant screw cap to open the bottle.
2. Check that the plunger of the appropriate oral dosing syringe is pushed all the way down.
3. Keep the bottle upright and insert the syringe firmly into the plastic adapter.
4. Slowly pull the plunger up to fill the dosing syringe with medicine.
5. Withdraw the prescribed dose of medicine.
6. Remove the syringe by gently twisting it out of the plastic adapter.
7. Push the entire dose out of the syringe, either directly into the mouth of the cat or dog. For cats, the dose can also mixed into the cat's food.
8. Close the bottle with the child-resistant screw cap after use. Store the syringe in the plastic tube for further use.

Note: If the prescribed dose is more than the maximum volume marked on the syringe, you will need to repeat steps 2 to 7 to administer the remaining amount of the prescribed dose.
Do not attempt to clean the oral dosing syringe (e.g. with water) in between uses.



10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store between 15°C and 30°C but not below 20°C for more than one month.
Storage in the refrigerator should be avoided.
Keep the bottle in the outer carton.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging of the 5 ml or 17 ml bottle: 70 days.
Shelf life after first opening the immediate packaging of the 50 ml bottle: 84 days.

The product contains oily components from natural origin which can become solid at lower temperatures. A jelly-like formation may occur below 20°C which is however reversible at temperatures up to 30°C. Minor flakes or a slight sediment may still be observed. However, this does neither affect the dosing nor the efficacy and safety of the product.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 00879/5018

Cardboard box with 1 bottle with 5 ml or 17 ml oral solution and one dispenser set (dip tube and a 1 ml syringe)..
Cardboard box with 1 bottle with 50 ml oral solution and two dispenser sets (dip tube and a 1 ml or 4 ml syringe).
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

PV.GBR@elancoah.com

Manufacturer responsible for batch release:
Elanco France, 26 Rue de la Chapelle, F-68330 Huningue, France

17. OTHER INFORMATION

UK (GB and Northern Ireland)
POM-V: To be supplied only on veterinary prescription

Gavin Hall

Approved 10 July 2024