PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atopica 50 mg soft capsules for dogs

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active Ingredient:
Each capsule contains 50 mg ciclosporin
Excipients include E120, E171, E307

3. PHARMACEUTICAL FORM

Soft capsule

4. PACKAGE SIZE

Box containing 15 capsules in 3 aluminium/aluminium blister packs
Box containing 30 capsules in 6 aluminium/aluminium blister packs
Box containing 60 capsules in 12 aluminium/aluminium blister packs

5. TARGET SPECIES

Dogs (7.5 up to 36 kg)

6. INDICATION(S)

For the treatment of chronic manifestations of atopic dermatitis in dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Before using this product please refer to leaflet for directions for use, contraindications and dosage.
Operator warnings
Wash hands after administration. In case of accidental ingestion of the capsule or its contents,

seek medical advice immediately and show the package leaflet or the label to the physician.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep the medicinal product in the blister pack.
Keep the blister pack in the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Please see the information in the package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4068

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister foil

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atopica 50 mg soft capsules for dogs

Ciclosporin

2. NAME OF THE MARKETING AUTHORISATION HOLDER

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

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

ATOPICA 10 mg soft capsules for dogs
ATOPICA 25 mg soft capsules for dogs
ATOPICA 50 mg soft capsules for dogs
ATOPICA 100 mg soft capsules for dogs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA

Manufacturer for the batch release:
Elanco France S.A.S., 26 Rue de la Chapelle, F-68330 Huningue, France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ATOPICA 10 mg soft capsules for dogs
ATOPICA 25 mg soft capsules for dogs
ATOPICA 50 mg soft capsules for dogs
ATOPICA 100 mg soft capsules for dogs

Ciclosporin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance:
Each capsule contains either 10 mg, 25 mg, 50 mg or 100 mg of ciclosporin.

Excipients:
ATOPICA 10 mg and 50 mg: E-120, E-171, E-307
ATOPICA 25 mg and 100 mg: E-120, E-171, E-172, E-307

4. INDICATION(S)

Treatment of chronic manifestations of atopic dermatitis in dogs.

Atopic dermatitis is one of the most common allergic skin diseases in dogs and is caused by allergens such as house dust mites or pollens which stimulate an exaggerated immune response in atopic dogs. The disease is chronic, recurrent and

requires lifelong management. Ciclosporin selectively acts on the immune cells involved in the allergic reaction. Ciclosporin reduces the inflammation and itching associated with atopic dermatitis.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to ciclosporin or one of the excipients.
For all capsule strengths, do not use in dogs less than six months of age or less than 2 kg in weight.
Do not use in cases 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.

6. ADVERSE REACTIONS

The occurrence of adverse reactions is uncommon. Gastrointestinal disturbances such as vomiting, mucoid or soft faeces and diarrhoea may occur. They are mild and transient and generally do not require the cessation of the treatment.
Other undesirable effects are rare and may include lethargy or hyperactivity, anorexia, mild to moderate gingival hyperplasia, skin reactions such as verruciform lesions or change of hair coat, red and swollen pinnae, muscle weakness or muscle cramps. These effects generally resolve spontaneously after treatment is stopped.
Very rarely diabetes mellitus has been observed, reported mainly in West Highland White Terriers.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs

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

The mean recommended dose of ciclosporin is 5 mg/kg body weight given orally according to the following scheme.

Bodyweight of the dog	Number of capsules given to obtain the recommended dose			
	ATOPICA 10 mg	ATOPICA 25 mg	ATOPICA 50 mg	ATOPICA 100 mg
2 to < 3 kg	1 capsule			
3 to < 4 kg	2 capsules			
4 to < 7.5 kg		1 capsule		
7.5 to < 15 kg			1 capsule	
15 to < 29 kg				1 capsule
29 kg to < 36 kg			3 capsules	
36 to 55 kg				2 capsules

ATOPICA 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, ATOPICA 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, ATOPICA may be given every 3 to 4 days. 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. 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, if advised to do so by your veterinarian. Upon recurrence of clinical signs, treatment should be resumed at daily dosing, and, as atopic dermatitis is a chronic disease, repeated treatment courses may be required.

9. ADVICE ON CORRECT ADMINISTRATION

ATOPICA should be given at least 2 hours before or after feeding as bioavailability is better in fasted animals.
Insert the capsule directly into the dog’s mouth.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children. Do not store above 25°C. Keep the medicinal product in the blister pack. Keep the blister pack in the outer carton. Do not use after the expiry date stated on the blister after EXP.

12. SPECIAL WARNING(S)

Consideration should be given to the use of other measures and/or treatments to control moderate to severe pruritus when initiating therapy with ciclosporin.

Special precautions for use
Clinical signs of atopic dermatitis such as itching and skin inflammation are not specific for this disease and therefore other causes of dermatitis such as ectoparasitic infestations, other allergies which cause dermatological signs (*e.g*. flea allergic dermatitis or food allergy) or bacterial and fungal infections should be ruled out before treatment is started.
It is good practice to treat flea infestations before and during treatment of atopic dermatitis.
It is recommended to clear bacterial and fungal infections before administering ATOPICA. However, infections occurring during treatment are not necessarily a reason for drug withdrawal, unless the infection is severe.
Your veterinarian will carry out a complete clinical examination before treatment. As ciclosporin inhibits T-lymphocytes and though it does not induce tumors, it may lead to increased incidences of clinically apparent malignancy. If lymphadenopathy (enlargement of the lymph glands) is observed during treatment, this should be regularly monitored.
Ciclosporin may affect the circulating levels of insulin. In dogs with signs suggestive of diabetes mellitus, glucose levels must be monitored. If signs of diabetes mellitus are observed following the use of Atopica, e.g. excessive thirst or abnormally large production of urine, the dose should be tapered or discontinued and veterinary care sought. The use of ATOPICA is not recommended in diabetic dogs.

Creatinine levels should be closely monitored in dogs with severe renal insufficiency.
Treatment with ATOPICA may interfere with vaccination efficacy. It is not recommended to vaccinate during treatment or within a two-week interval before or after administration of the product.
It is not recommended to use other immunosuppressive agents concomitantly.

Use during pregnancy or lactation
The safety of ATOPICA has not been studied in breeding male dogs nor in pregnant or lactating female dogs. Ciclosporin passes the placenta barrier and is excreted via milk, therefore the treatment of lactating bitches is not recommended. Your veterinarian should be advised if your dog is a breeding animal, so that a risk/benefit assessment can be made.

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 ATOPICA may be required. The toxicity of some medications may be

increased by administration with ciclosporin. Consult your veterinarian prior to administering other products during ATOPICA therapy.

Overdose
No undesirable effects beyond those that were seen under recommended treatment have been observed in the dog with a single oral dose of up to 6 times of what is recommended.
There is no specific antidote and in case of signs of overdose the dog should be treated symptomatically. The signs are reversible within 2 months following cessation of treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Wash hands after administration.
In the case of accidental ingestion of the capsule or its contents, seek medical advice immediately and show the package insert or the label to the physician.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

Boxes contain either 15, 30 or 60 capsules. Not all pack sizes may be marketed.

Approved 18 December 2020