ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTONBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atopica 10 mg soft capsules

2. STATEMENT OF ACTIVE SUBSTANCES

10 mg ciclosporin/capsule

3. PACKAGE SIZE

15, 30, 60 soft capsules.

4. TARGET SPECIES

Dogs (from 2 to 4 kg).

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Keep the veterinary medicinal product in the blister pack.
Keep the blister pack 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 OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 52127/3024

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atopica

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

ciclosporin 10 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Atopica 10 mg soft capsules for dogs

2. Composition

Each capsule contains:
Active substance:

Atopica capsules	ciclosporin (mg)
for dogs (2 – 4 kg)	10
for dogs (4 – 7.5 kg)	25
for dogs (7.5 – 36 kg)	50
for dogs (15 – 55 kg)	100

Excipients:
Atopica 10 mg and 50 mg: α-tocopherol (E-120): 0.250 mg, Titanium dioxide (E-171): 2.120 mg, Carminic acid (E-307): <1.00 µg
Atopica 25 mg and 100 mg: α-tocopherol (E-120): 0.250 mg, Iron oxide black (E-172): 0.105 mg
Titanium dioxide (E-171): 2.120 mg, Carminic acid (E-307): <1.00 µg

10 mg capsule: Yellow-white oval soft capsules bearing the imprint: NVR 10 mg.
25 mg capsule: Blue-grey oval soft capsules bearing the imprint: NVR 25 mg.
50 mg capsule: Yellow-white oblong soft capsules bearing the imprint: NVR 50 mg.
100 mg capsule: Blue-grey oblong soft capsules bearing the imprint: NVR 100 mg.

3. Target species

Dogs.

4. Indications for use

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. Special warnings

Special warnings:
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 safe use in the target species:
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 veterinary medicinal product. 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 veterinary medicinal product, e.g. excessive thirst or abnormally large production of urine, the dose should be tapered or discontinued and veterinary care sought.

The use of veterinary medicinal product is not recommended in diabetic dogs. Creatinine levels should be closely monitored in dogs with severe renal insufficiency.

Treatment with veterinary medicinal product 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.

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.

Pregnancy and lactation:
The safety of veterinary medicinal product 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 veterinary medicinal product may be required. The toxicity of some medications may be increased by administration with ciclosporin. Consult your veterinarian prior to administering other products during veterinary medicinal product's 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.

7. Adverse events

Dogs:

Uncommon (1 to 10 animals / 1,000 animals treated):	Digestive tract disorders (such as Vomiting, Mucous stool, Loose stool, Diarrhoea)[1].
Rare (1 to 10 animals / 10,000 animals treated):	Lethargy[2], Anorexia[2]; Hyperactivity[2]; Gingival hyperplasia (mild to moderate)[2]; 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 mellitus3.

[1] Generally mild and transient and do not require the cessation of the treatment
[2] Generally resolve spontaneously after treatment is stopped
[3] 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, routes and method of administration

Oral use.
To ensure a correct dosage, body weight should be determined as accurately as possible.

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			3 capsules	
36 to 55 kg				2 capsules

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, 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, veterinary medicinal product 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

Veterinary medicinal product 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 periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25°C.

Keep the veterinary medicinal product in the blister pack. Keep the blister pack in the outer carton.
Do not use this veterinary medicinal product after the expiry date stated on the blister after Exp. The expiry date refers to the last day of that month.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater or <household waste>.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 52127/3024

Aluminium/Aluminium blisters containing 5 soft capsules.
Cardboard box of 15, 30 or 60 soft capsules.
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 GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany
PV.XXI@elancoah.com
Tel: +44 3308221732

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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Gavin Hall
Approved: 28 April 2026