# PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box)

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Modulis 100 mg/ml oral solution for dogs

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
**Active substance:**
Ciclosporin 100 mg

## 3. PACKAGE SIZE

5 ml
15 ml
30 ml
50 ml

## 4. TARGET SPECIES

Dogs

## 5. INDICATIONS

## 6. ROUTES OF ADMINISTRATION

Oral use

## 7. WITHDRAWAL PERIODS

## 8. EXPIRY DATE

EXP {mm/yyyy}
Once opened, use by …
Shelf-life after first opening the immediate packaging: 3 months

## 9. SPECIAL STORAGE PRECAUTIONS

Storage in the refrigerator should be avoided. Keep the bottle in the outer carton. The product contains fat 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.

## 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

Ceva Sante Animale

## 14. MARKETING AUTHORISATION NUMBERS

Vm 14966/5075
Vm 14966/3074

## 15. BATCH NUMBER

Lot

# MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

**Glass bottle**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Modulis

## 2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Ciclosporin……100 mg/mL

## 3. BATCH NUMBER

Lot {number}

## 4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use the product within 3 months.

# PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

## PACKAGE LEAFLET

### 1. Name of the veterinary medicinal product

Modulis 100 mg/ml oral solution for dogs

### 2. Composition

Each ml contains:

**Active substance:**
Ciclosporin 100mg

**Excipients:**
all-rac-a-tocopherol (E-307) 1 mg

Clear to slightly yellow opalescent solution. A veil, minor flakes or slight sediment may be observed.

### 3. Target species

Dogs

### 4. Indications for use

Treatment of chronic manifestations of atopic dermatitis in dogs.
This is a type of allergic skin disease in dogs and is caused by allergens such as house dust mites or pollens which stimulate an excessive immune response. Ciclosporin reduces the inflammation and itching associated with atopic dermatitis.

### 5. Contraindications

Do not use in cases of hypersensitivity to ciclosporin or to any of the excipients. 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 (see also sections “Special precautions for use” and “Interaction with other medicinal products”).

### 6. Special warnings

Special warnings
Consideration should be given to the use of other measures and/or treatment 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 pruritus 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 the veterinary medicinal product. However, infections occurring during treatment are not necessarily a reason for drug withdrawal, unless the infection is severe.

A complete clinical examination should be performed before treatment. As ciclosporin inhibits T-lymphocytes and though it does not induce tumors, it may lead to increased incidences of clinically apparent malignancy due to the decrease in antitumor immune response. Lymphadenopathy observed on treatment with ciclosporin should be regularly monitored.

In laboratory animals, ciclosporin is liable to affect the circulating levels of insulin and to cause an increase in glycaemia. In the presence of suggestive signs of diabetes mellitus, the effect of treatment on glycaemia must be monitored. If signs of diabetes mellitus are observed following the use of the product, e.g. polyuria or polydipsia, the dose should be tapered or discontinued and veterinary care sought. The use of ciclosporin is not recommended in diabetic dogs.

Closely monitor creatinine levels in dogs with severe renal insufficiency.

Particular attention must be paid to vaccination. Treatment with the veterinary medicinal product may interfere with vaccination efficacy. In the case of inactivated vaccines, it is not recommended to vaccinate during treatment or within a two-week interval before or after administration of the product. For live vaccines see also section “Contraindications.

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:

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. 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 product.

Irritation to eyes is unlikely. As precautionary measure avoid contact with eyes. In case of contact, rinse thoroughly with clean water. Wash hands and any exposed skin after use.

Pregnancy and lactation:

The safety of the drug has neither been studied in breeding male dogs nor in pregnant or lactating female dogs. In the absence of such studies in the dog, it is recommended to use the drug in breeding dogs only upon a positive risk/benefit assessment by the veterinarian. Ciclosporin passes the placenta barrier and is excreted via milk. Therefore the treatment of lactating 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 veterinary medicinal product may be required. Ketoconazole at 5-10 mg/kg is known to increase the blood concentration of ciclosporin in dogs up to five-fold, which is considered to be clinically relevant.
During concomitant use of ketoconazole and ciclosporin the veterinarian should consider as a practical measure to double the treatment interval if the dog is on a daily treatment regime.
Macrolides as erythromycin may increase the plasma levels of ciclosporin up to twofold.
Certain inducers of cytochrome P450, anticonvulsants and antibiotics (e.g. trimethoprim/sulfadimidine) may lower the plasma concentration of ciclosporin.
Ciclosporin is a substrate and an inhibitor of the MDR1 P-glycoprotein transporter. Therefore, the co-administration of ciclosporin with P-glycoprotein substrates such as macrocyclic lactones (e.g. ivermectin and milbemycin) could decrease the efflux of such drugs from blood-brain barrier cells, potentially resulting in signs of Central Nervous System toxicity.
Ciclosporin can increase the nephrotoxicity of aminoglycoside antibiotics and trimethoprim. The concomitant use of ciclosporin is not recommended with these active ingredients.

Particular attention must be paid to vaccination (see sections “Contraindications” and “Special precautions for use”). Concomitant use of immunosuppressive agents: see section “Special precautions for use”.

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.
In addition to what was seen under recommended dosage, the following adverse reactions were seen in case of overdose for 3 months or more at 4 times the mean recommended dosage: hyperkeratotic areas especially on the pinnae, callous-like lesions of the foot pads, weight loss or reduced weight gain, hypertrichosis, increased erythrocyte sedimentation rate, decreased eosinophil values. Frequency and severity of these signs are dose dependent.
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.

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

## 7. Adverse events

Dogs:

| | |
|---|---|
| Common<br>(1 to 10 animals / 100 animals treated): | Mucous stool[1], soft stool[1] |
| Uncommon<br>(1 to 10 animals / 1,000 animals treated): | Hyperactivity[1]<br>Skin lesion[1] (verruciform lesion, hair change)<br>Muscle weakness[1], musculoskeletal cramp[1] |
| Rare<br>(1 to 10 animals / 10,000 animals treated): | Vomiting[2] |
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Diarrhoea[2]<br>Lethargy[2], anorexia[2]<br>Gingival hyperlasia[2]<br>Pinnal irritation[2]<br>Diabetes mellitus[3] |

[1]These signs are mild and transient and generally do not require the cessation of the treatment.
[2]These signs are mild and transient and generally do not require the cessation of the treatment.[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 at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

## 8. Dosage for each species, routes

For oral use

Before starting treatment, an evaluation of all alternative treatment options should be made. The mean recommended dose of ciclosporin is 5 mg/kg body weight

corresponding to 0.5 ml of solution for 10 kg of body weight.

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 preparation can then be given every other day as a maintenance dose. The veterinarian should perform a clinical assessment at regular intervals and adjust the frequency of administration to the clinical response obtained.
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. The lowest effective frequency of dosing should be used to maintain the remission of clinical signs.
Adjunct treatment (e.g. medicated shampoos, fatty acids) may be considered before reducing the dosing interval. Patients should be regularly re-evaluated and alternative treatment options reviewed.
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.

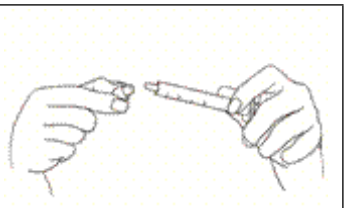
## 9. Advice on correct administration

The veterinary medicinal product should be given at least 2 hours before or after feeding.
The product is administered directly into the mouth.

Instructions for use
Push down and unscrew bottle top.
Insert the dosing syringe into the plastic adapter.

Turn the bottle/syringe upside down and slowly pull the plunger down
until the white line on the plunger corresponds to the dose prescribed by your veterinarian. The syringe is graduated in kg and ml.

By pushing the plunger in, empty the contents of the syringe directly into the mouth.
Introduce the syringe either to the side of the mouth or over the tongue.

| | |
|---|---|
| If necessary, wipe the outside of the syringe with a dry tissue and dispose of used tissue immediately. Close the bottle and insert the syringe into the specific cap to protect from any contamination and to avoid any spillage of remaining product. |  |

**For the 5 and 15 ml vials**
Volume to be administered using 1ml syringe: 0.05 ml/kg i;e 1 graduation/kg.
**For the 30 and 50 ml vials**

Volume to be administered using 2ml syringe: 0.1 ml/2kg i;e 1 graduation/2kg.

## 10. Withdrawal periods

Not applicable

## 11. Special storage precautions

Keep out of the sight and reach of children.
Keep the bottle in the outer carton.

Discard any remaining product 3 months after opening.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial label, after “EXP”. The expiry date refers to the last day of that month.

Storage in the refrigerator should be avoided.
The product contains fat 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.

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 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 14966/5075
Vm 14966/3074

Pack sizes:
5 ml bottle with 1 ml oral syringe in a cardboard box
15 ml bottle with 1 ml oral syringe in a cardboard box
30 ml bottle with 2 ml oral syringe in a cardboard box
50 ml bottle with 2 ml oral syringe in a cardboard box

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:
Ceva Sante Animale
8 rue de Logrono
33500 Libourne
France

Contact details to report suspected adverse reactions:
Ceva Animal Health Ltd
Explorer House, Mercury Park
Wycombe Lane, Wooburn Green
High Wycombe
Buckinghamshire
HP10 0HH
United Kingdom
Tel: 00800 35 22 11 51
Email for the reporting of adverse events: pharmacovigilance@ceva.com

Manufacturer responsible for batch release:
Ceva Santé Animale, Boulevard de la Communication, Zone Autoroutière, 53950 LOUVERNE
France

Laboratoires Biové, 3 Rue de Lorraine 62510 Arques
France

## 17. Other information

| | |
|---|---|
| POM-V | For animal treatment only |

*Gavin Hall*

Approved: 22 April 2026