SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cyclavance 100 mg/ml oral solution for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Ciclosporin 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
All-rac-α-tocopherol (E-307)	1.00 mg
Glycerol monolinoleate	
Ethanol, anhydrous (E-1510)	
Macrogolglycerol hydroxystearate	
Propylene glycol (E-1520)	

Clear to slightly yellow solution

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
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 3.5 “Special precautions for use” and 3.8 “Interaction with other medicinal products and other forms of interaction”).

Do not use in dogs less than six months of age or less than 2 kg in weight.

Do not use in cats infected with Feline Leukemia Virus (FeLV) or Feline Immunodeficiency Virus (FIV).

3.4 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Clinical signs of atopic dermatitis in dogs and allergic dermatitis in cats such as pruritus and skin inflammation are not specific for these diseases. 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 or allergic dermatitis.

A complete clinical examination should be performed prior to treatment. 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 antitumour immune response. The potentially increased risk of tumour progression must be weighed against the clinical benefit. If lymphadenopathy is observed in animals being treated with ciclosporin, further clinical investigations are recommended and treatment discontinued if necessary.

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.

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

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 veterinary medicinal product. For live vaccines see also section 3.3 “Contraindications”.

It is not recommended to use other immunosuppressive agents concomitantly.
Dogs:

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 the cats 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 indoors, avoid raw meat or scavenging). However, in a controlled laboratory study, treatment with ciclosporin did not reactivate oocyst shedding in cats previously exposed to *T. gondii*. In cases of clinical toxoplasmosis or other serious systemic illness, stop treatment with ciclosporin and initiate appropriate therapy.

Clinical studies in cats have shown that decreased appetite and weight loss may occur during ciclosporin treatment. Monitoring of body weight is recommended. Significant reduction in body weight may result in hepatic lipidosis. 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 veterinary medicinal product may lead to nausea and/or vomiting. To avoid accidental ingestion, the veterinary medicinal product must be used and kept out of reach of children. Do not leave unattended filled oral syringes 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 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 any exposed skin after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Regarding malignancy, please see sections 3.3 “Contraindications” and 3.5 “Special precautions for use”.
Dogs:

Uncommon (1 to 10 animals / 1,000 animals treated):	Digestive tract disorders (e.g. vomiting, mucous stool, loose stool and diarrhoea)[2,4], Lethargy[4], Anorexia[4] Hyperactivity[4], Gingival hyperplasia[1,4], Skin reactions (e.g. verruciform lesion or hair change)[4], Pinnal reddening and Pinnal oedema[4], Muscle weakness or Muscle cramps[4]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Diabetes mellitus[3]
Undetermined Frequency	Hypersalivation[2,4]

[1]Mild and moderate.
[2]Mild and transient and generally do not require the cessation of the treatment.
[3]Especially in West Highland White Terriers.
[4]Generally resolve spontaneously after treatment is stopped.

Cats:

Very common (>1 animal / 10 animals treated):	Digestive tract disorders (e.g. vomiting and diarrhoea), Weight loss[1]
Common (1 to 10 animals / 100 animals treated):	Increased appetite, Lethargy, Anorexia, Hypersalivation, Hyperactivity, Polydipsia, Gingival hyperplasia and Lymphopaenia[2]

[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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
In laboratory animals, at doses which induce maternal toxicity (rats at 30 mg/kg BW and rabbits at 100 mg/kg BW) ciclosporin was embryo- and foetotoxic, as indicated by increased pre- and postnatal mortality and reduced foetal weight together with skeletal retardations. In the well-tolerated dose range (rats at up to 17 mg/kg BW and rabbits at up to 30 mg/kg BW) ciclosporin was without embryolethal or teratogenic effects. Therefore the use is not recommended during pregnancy of bitches and queens.

Lactation:
In laboratory animals ciclosporin crosses the placenta barrier and is excreted via milk. Therefore the treatment of lactating bitches and queens is not recommended.

Fertility:
The safety of the veterinary medicinal product has neither been studied in male dogs or cats used for breeding. In the absence of such studies, it is recommended to use the veterinary medicinal product in breeding animals only upon a positive benefit/risk assessment by the responsible veterinarian.

3.8 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 particular cytochrome P450 (CYP3A4). In certain clinically justified cases, an adjustment of the dosage of the veterinary medicinal product may be required.

The compound class of azoles (e.g. ketoconazole) is known to increase the blood concentration of ciclosporin in dogs and cats, which is considered to be clinically relevant. Ketoconazole at 5-10 mg/kg is known to increase the blood concentration of ciclosporin in dogs up to five-fold. 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 such 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 CNS 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 section 3.3 “Contraindications” and 3.5 “Special precautions for use”) and to concomitant use of other immunosuppressive agents (see section 3.5 “Special precautions for use”).

3.9 Administration routes and dosage

For oral use.

Before starting treatment, an evaluation of all alternative treatment options should be made.

Before administration, the body weight of animals has to be accurately determined.

Dogs:

The recommended dose of ciclosporin is 5 mg/kg body weight (0.05 ml of oral solution per kg BW) and should initially be administered daily. The frequency of administration should subsequently be reduced depending on the response.

The veterinary medicinal product should initially be given daily until a satisfactory clinical improvement is seen. This will generally be the case within 4-8 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 second day. 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 second day dosing, the 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.

Patients should be regularly re-evaluated and alternative treatment options reviewed. Adjunct treatment (e.g. medicated shampoos, fatty acids) may be considered before reducing the dosing interval.
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.

Dosages for dogs:

At standard dosage of 5mg/kg

Weight (kg)		**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**
Dosage (ml)		0.1	0.15	0.2	0.25	0.3	0.35	0.4	0.45	0.5
Weight (kg)	**11**	**12**	**13**	**14**	**15**	**16**	**17**	**18**	**19**	**20**
Dosage (ml)	0.55	0.6	0.65	0.7	0.75	0.8	0.85	0.9	0.95	1

Weight (kg)	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**
Dosage (ml)	1.05	1.1	1.15	1.2	1.25	1.3	1.35	1.4	1.45	1.5
Weight (kg)	**31**	**32**	**33**	**34**	**35**	**36**	**37**	**38**	**39**	**40**
Dosage (ml)	1.55	1.6	1.65	1.7	1.75	1.8	1.85	1.9	1.95	2
Weight (kg)	**41**	**42**	**43**	**44**	**45**	**46**	**47**	**48**	**49**	**50**
Dosage (ml)	2.05	2.1	2.15	2.2	2.25	2.3	2.35	2.4	2.45	2.5
Weight (kg)	**51**	**52**	**53**	**54**	**55**	**56**	**57**	**58**	**59**	**60**
Dosage (ml)	2.55	2.6	2.65	2.7	2.75	2.8	2.85	2.9	2.95	3
Weight (kg)	**61**	**62**	**63**	**64**	**65**	**66**	**67**	**68**	**69**	**70**
Dosage (ml)	3.05	3.1	3.15	3.2	3.25	3.3	3.35	3.4	3.45	3.5
Weight (kg)	**71**	**72**	**73**	**74**	**75**	**76**	**77**	**78**	**79**	**80**
Dosage (ml)	3.55	3.6	3.65	3.7	3.75	3.8	3.85	3.9	3.95	4

PRIMARY PACKAGING TYPE 1
For the 30 and 60 ml bottles, either the 1 ml oral syringe (graduated every 0.05 ml) or
the 2 ml oral syringe (graduated every 0.1 ml) can be used to achieve the dose stated above, determined according to bodyweight.

PRIMARY PACKAGING TYPE 2
For the 30 and 50 ml bottles, either the 1 ml oral syringe (graduated every 0.05 ml) or
the 3 ml oral syringe (graduated every 0.1 ml) can be used to achieve the dose stated above, determined according to bodyweight.

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

The veterinary medicinal 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. Severe prolonged pruritus may induce a state of anxiety and subsequent excessive grooming behaviour. In such

cases, despite an improvement in pruritus upon administration of the treatment, the resolution of self-induced alopecia may be delayed.

Once the clinical signs of allergic dermatitis are satisfactorily controlled, the veterinary medicinal product can then be given every second day. In some cases where the clinical signs are controlled with every second day dosing, the 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. Patients should be regularly re-evaluated and alternative treatment options reviewed. 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.

The veterinary medicinal 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 oral syringe directly into the cat's mouth and delivering the entire dose. In case the cat only partially consumes the product mixed with food, administration of the veterinary medicinal product with the oral syringe should be resumed only the next day. Any uneaten medicated cat food must be disposed of immediately and the bowl washed thoroughly.

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

Dosage for cats:

As the efficacy and safety of ciclosporin have not been assessed in cats weighing less than 2.3 kg (see section 4.5), administration of the veterinary medicinal product to cats weighing less than 2.3 kg should be according to a benefit-risk assessment by the responsible veterinarian.
At standard dosage of 7 mg/kg

Weight (kg)	**2.1**	**2.9**	**3.6**	**4.3**	**5.0**	**5.7**	**6.4**	**7.1**
Dosage (ml)	0.15	0.20	0.25	0.30	0.35	0.40	0.45	0.50

Weight (kg)	**7.9**	**8.6**	**9.3**	**10.0**	**10.7**	**11.4**	**12.1**	**12.8**	**13.6**	**14.3**
Dosage (ml)	0.55	0.60	0.65	0.70	0.75	0.80	0.85	0.90	0.95	1.00

PRIMARY PACKAGING TYPE 1
For the 30 and 60 ml bottles, either the 1 ml oral syringe (graduated every 0.05 ml) or
the 2 ml oral syringe (graduated every 0.1 ml) can be used to achieve the dose stated above, determined according to bodyweight.

PRIMARY PACKAGING TYPE 2
For the 30 and 50 ml bottles, either the 1 ml oral syringe (graduated every 0.05 ml) or
the 3 ml oral syringe (graduated every 0.1 ml) can be used to achieve the dose stated above, determined according to bodyweight.

INSTRUCTIONS FOR USE

Dogs: The veterinary medicinal product should be given at least 2 hours before or after feeding. Insert the oral syringe directly into the dog’s mouth.
Cats: The product can be given either mixed with food or directly into the mouth in cats.

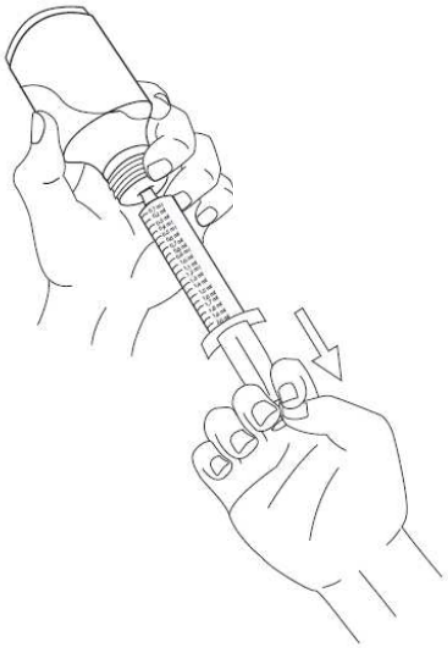
PRIMARY PACKAGING TYPE 1

1 Push and turn the child-resistant screw cap to open the bottle.

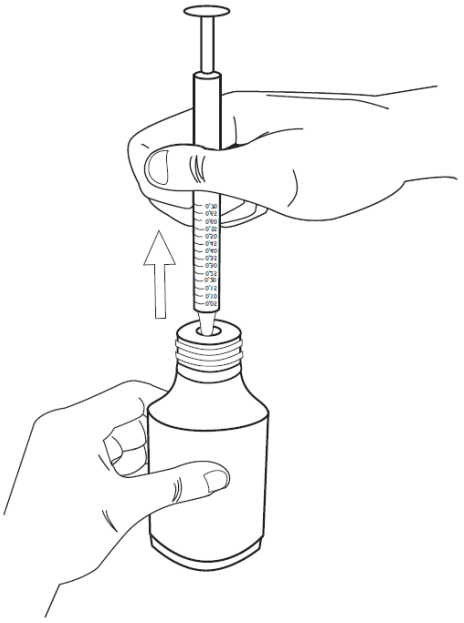
Always close the bottle with the child-resistant screw cap after use.

2 Keep the bottle upright and insert the oral dosing syringe firmly into the plastic adapter.

3 Turn the bottle upside down and slowly pull the plunger up so that the oral dosing syringe fills with the product.
Withdraw the dose of medicine prescribed by your veterinarian.



4 Return the bottle to its upright position and remove the oral dosing syringe by gently twisting it out of the plastic adapter.



5 You can now introduce the syringe in the mouth of your animal and push the medicine out of the syringe.
Do not rinse or clean the oral dosing syringe between uses.

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.

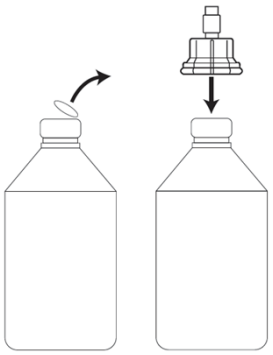
Note: For cats, you can also give the product mixed with food

6 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.

Keep out of the sight and reach of children

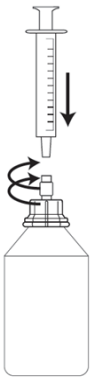
PRIMARY PACKAGING TYPE 2

1 Retrieve the plastic cap and insert firmly the plastic dispenser.

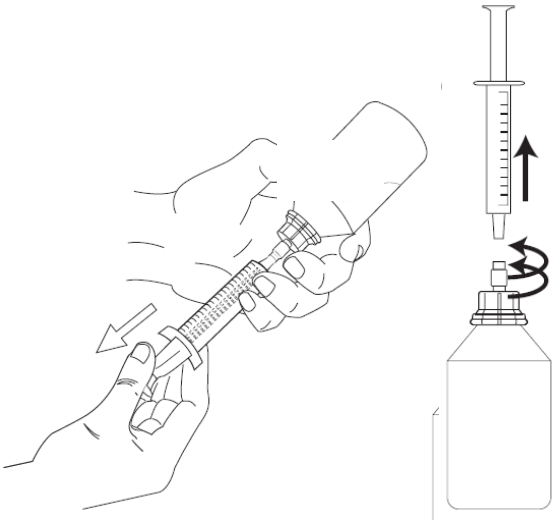


The plastic dispenser should remain in place.

2 Keep the bottle upright and insert the oral dosing syringe firmly into the plastic dispenser.



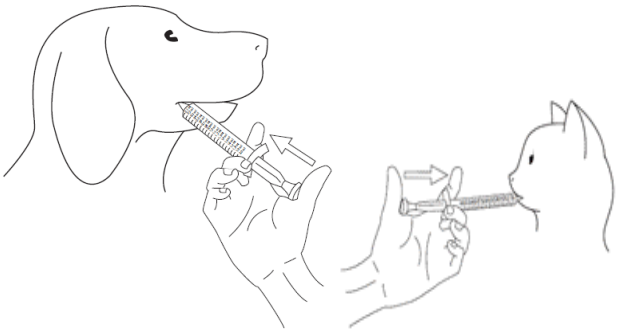
3 Turn the bottle upside down and slowly pull the plunger up so that the oral dosing syringe fills with the product.
Withdraw the dose of medicine prescribed by your veterinarian.



Return the bottle to its upright position and remove the oral dosing syringe by gently twisting it out of the plastic dispenser.

4 You can now introduce the syringe in the mouth of your animal and push the medicine out of the syringe.

Do not rinse or clean the oral dosing syringe between uses.



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.

Note: For cats, you can also give the product mixed with food

Keep out of the sight and reach of children

If necessary, the user can wipe the outside of the oral syringe with a dry tissue and dispose of used tissue immediately.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

There is no specific antidote and in case of signs of overdose the animal should be treated symptomatically.

Dogs:
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.
The signs are reversible within 2 months following cessation of treatment.

Cats:
The following adverse events were seen in the case of repeated administration for 56 days at 24 mg/kg (more than 3x the recommended dose) or for 6 months at up to 40 mg/kg (more than 5x the recommended dose): loose/soft faeces, vomiting, mild to moderate increases in absolute neutrophil counts, fibrinogen, activated partial thromboplastin time (APTT), slight increases in blood glucose and reversible gingival hypertrophy. Increased appetite was observed for both dose regimens. A transient increase followed by a decrease in lymphocyte counts was observed in treated cats, combined with a greater occurrence of palpable small peripheral lymph nodes. This may reflect immunosuppression following prolonged exposure to ciclosporin. APTT was prolonged in cats administered at least twice the recommended dose of ciclosporin. The frequency and severity of these signs were generally dose and time dependent. At 3x the recommended dose administered daily for nearly 6 months, changes in ECG (conduction disturbances) commonly occur. They are transient and not associated with clinical signs. Anorexia, recumbency, loss of skin elasticity, few or absent faeces, thin and closed eye lids may be observed in sporadic cases at 5x the recommended dose.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QL04AD01.

4.2 Pharmacodynamics

Ciclosporin (also known as cyclosporin, cyclosporine, cyclosporine A, CsA) is a selective immunosuppressor. It is a cyclic polypeptide consisting of 11 amino acids, has a molecular weight of 1203 daltons and acts specifically and reversibly on T lymphocytes.

Ciclosporin exerts anti-inflammatory and antipruritic effects in the treatment of allergic and atopic dermatitis. Ciclosporin has been shown to preferentially inhibit the activation of T-lymphocytes on antigenic stimulation by impairing the production of IL-2 and other T-cell derived cytokines. Ciclosporin also has the capacity to inhibit the antigen-presenting function of the skin immune system. It likewise blocks the recruitment and activation of eosinophils, the production of cytokines by keratinocytes, the functions of Langerhans cells, the degranulation of mast cells and therefore the release of histamine and pro-inflammatory cytokines.

Ciclosporin does not depress haematopoiesis and has no effect on the function of phagocytic cells.

4.3 Pharmacokinetics

Dogs:

Absorption
The bioavailability of ciclosporin is about 35%. The peak plasma concentration is reached within 1 to 2 hours. The bioavailability is better and less subject to individual variations if ciclosporin is administered to fasted animals rather than at mealtimes.

Distribution
The volume of distribution is about 7.8 L/kg. Ciclosporin is widely distributed to all tissues. Following repeated daily administration to dogs ciclosporin concentration in the skin is several times higher than in blood.

Metabolism
Unchanged ciclosporin represents about 25% of circulating blood concentrations in the course of the first 24 hours.
Ciclosporin is metabolised mainly in the liver by cytochrome P450 (CYP3A4), but also in the intestine. Metabolism takes place essentially in the form of hydroxylation and demethylation, leading to metabolites with little or no activity.

Elimination
Elimination is mainly via the faeces. Only 10% is excreted in the urine, mostly in the form of metabolites.
No significant accumulation was observed in blood of dogs treated for one year.

Cats:

Absorption:
The bioavailability of orally administered Ciclosporin is between 25 and 29% in cats. The peak blood concentrations is generally reached within 1 to 2 hours when given to fasted cats. Blood drug concentration-time curves are not dose proportional at dose levels greater than the recommended dose. There is a less than proportional increase in Cmax and AUC over the dose range 8 to 40 mg/kg.

Distribution
The volume of distribution at steady state is about 1.7-2.1 L/kg.

Metabolism
Ciclosporin is metabolised in the liver by cytochrome P450 3A enzymes.

Elimination
The terminal elimination phase half-life is 8-11 h.
There is no significant accumulation of ciclosporin beyond the first week of treatment.

In the cat, there are large inter-individual variations in blood ciclosporin concentrations. At the recommended dosage, ciclosporin plasma concentrations are not predictive of the clinical response, therefore monitoring of blood levels is not recommended.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 6 months.

5.3 Special precautions for storage

Keep the bottle in the outer carton.
Do not refrigerate.
A jelly-like formation may occur below 15°C which is however reversible at temperatures up to 25°C without affecting the quality of the product.

After first opening: Do not store above 25°C.

5.4 Nature and composition of immediate packaging

Packaging 1:

Amber glass (type III) bottles closed with a child resistant HDPE screw cap including a plastic adapter (HDPE).

5 ml bottle, with a dispenser set consisting of a 1 ml PE oral syringe graduated in increments of 0.05 ml, packaged in a cardboard box.
15 ml bottle, with a dispenser set consisting of a 1 ml PE oral syringe graduated in increments of 0.05 ml, packaged in a cardboard box.
30 ml bottle, with two dispenser sets consisting of both 1 ml and 2 ml PE oral syringes graduated in increments of respectively 0.05 ml and 0.1 ml, packaged in a cardboard box.

60 ml bottle, with two dispenser sets consisting of both 1 ml and 2 ml PE oral syringes graduated in increments of respectively 0.05 ml and 0.1 ml, packaged in a cardboard box.

Packaging 2:

Amber glass (type III) bottles closed with a 20 mm bromobutyl stopper and an aluminum cap with flip-off.

5 ml bottle with a dispenser set consisting of a polycarbonate dispenser cap with a silicone valve and a 1 ml polypropylene oral syringe graduated in increments of 0.05 ml, packaged in a cardboard box.
15 ml bottle with a dispenser set consisting of a polycarbonate dispenser cap with a silicone valve and a 1 ml polypropylene oral syringe graduated in increments of 0.05 mL, packaged in a cardboard box.
30 ml bottle, with two dispenser sets consisting of a polycarbonate dispenser cap with a silicone valve and both 1 ml and 3 ml polypropylene oral syringes graduated in increments of respectively 0.05 ml and 0.1 ml, packaged in a cardboard box.
50 ml bottle, with two dispenser sets consisting of a polycarbonate dispenser cap with a silicone valve and both 1 ml and 3 ml polypropylene oral syringes graduated in increments of respectively 0.05 ml and 0.1 ml, packaged in a cardboard box.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue 2065m LID
06516 Carros
France

7. MARKETING AUTHORISATION NUMBER

Vm 05653/3015

8. DATE OF FIRST AUTHORISATION

03 April 2014

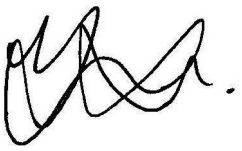
9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).



Approved: 04 April 2024