1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hedylon 5 mg tablets for dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:
Prednisolone 5 mg

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Maize starch
Pre-gelatinised starch
Colloidal anhydrous silica
Talc
Magnesium stearate

White round tablets with a cross-shaped break line on one side and number 5 engraved on the reverse. Tablets can be divided into 2 or 4 equal parts.

3. CLINICAL INFORMATION

3.1 Target species

Dogs and cats.

3.2 Indications for use for each target species

For the symptomatic treatment or as adjunct treatment of inflammatory and immune-mediated diseases in dogs and cats.

3.3 Contraindications

Do not use in animals with:
- Viral, mycotic or parasitic infections that are not controlled with an appropriate treatment
- Diabetes mellitus
- Hyperadrenocorticism
- Osteoporosis
- Heart failure
- Renal insufficiency
- Corneal ulceration
- Gastro-intestinal ulceration
- Glaucoma

Do not use concomitantly with attenuated live vaccines
Do not use in cases of hypersensitivity to the active substance, to other corticosteroids, or to any of the excipients.
See also sections 3.7 and 3.8.

3.4 Special warnings

Corticoid administration is to induce an improvement in clinical signs rather than a cure. The treatment should be combined with treatment of the underlying disease and/or environmental control.

3.5 Special precautions for use

Special precautions for safe use in the target species:

In cases where a bacterial infection is present the veterinary medicinal product should be used in association with suitable antibacterial therapy. Pharmacologically-active dose levels may result in adrenal insufficiency. This may become apparent particularly after withdrawal of corticosteroid treatment. This effect may be minimised by institution of alternate-day therapy if practical. The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency (see section 3.9).
Corticoids such as prednisolone, exacerbate protein catabolism. Consequently, the veterinary medicinal product should be carefully administered in old or malnourished animals.
Corticoids such as prednisolone should be used with caution in patients with hypertension, epilepsy, burns, previous steroid myopathy, in immunocompromised animals and in young animals as corticosteroids may induce a delayed growth.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Prednisolone or other corticosteroids may cause hypersensitivity (allergic reactions). People with known hypersensitivity to prednisolone or other corticosteroids, or any of the excipients, should avoid contact with the veterinary medicinal product.
To avoid accidental ingestion, particularly by a child, unused part-tablets should be returned to the open blister space and inserted back into the carton. In case of accidental ingestion, especially by a child, seek medical advice immediately and show the package leaflet or the label to the physician.
Corticosteroids can cause foetal malformations; therefore, it is recommended that pregnant women avoid contact with the veterinary medicinal product.
Immediately wash hands thoroughly after handling the tablets.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs and cats:

Very common (>1 animal / 10 animals treated):	Elevated triglyceride[1] Hypocortisolaemia[2]
Undetermined frequency (cannot be determined from the available data):	Adrenal insufficiency[3] Hyperadrenocorticism (iatrogenic), Cushing's disease (iatrogenic), diabetes mellitus, hypothyroidism, hyperparathyroidism Elevated alkaline phosphatase (SAP), elevated liver enzymes, decreased aspartate transaminase (AST), decreased lactic acid dehydrogenase (LDH), hyperalbuminaemia, hypokalaemia[4] Neutrophilia, eosinopenia, lymphopenia

	Polyuria[5] Polydipsia[5], polyphagia[5], sodium and water retention[4], increased weight[1], redistribution of body fat[1], wastage[1], delayed healing Cutaneous calcinosis[6], skin thinning Opportunistic infection[7] Gastrointestinal ulceration[8], pancreatitis Inhibition of longitudinal growth of bones, osteoporosis[1], muscle weakness[1], muscle atrophy[1] Behavioural disorders (excitation, depression)

[1] Can be a part of possible iatrogenic hyperadrenocorticism (Cushing's disease), which involves significant alteration of fat, carbohydrate, protein and mineral metabolism
[2] Result of effective doses supressing the hypothalamic-pituitary-adrenal axis
[3] Following cessation of treatment. It may render the animal unable to deal adequately with stressful situations
[4] In long term use
[5] When systemically administered, particularly during the early stages of therapy
[6] After systemic use
[7] The immunosuppressant action of corticosteroids may weaken resistance to or exacerbate existing infections
[8] May be exacerbated by steroids in animals given Non-steroidal Anti-inflammatory Drugs and in animals with spinal cord trauma

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:
Do not use during pregnancy. Laboratory studies have shown evidence of foetal abnormalities during early pregnancy and abortion or early parturition during the later stages of pregnancy.

Lactation:
Glucocorticoids are excreted in the milk and may result in growth impairment in suckling young animals. Use only according to the benefit-risk assessment by the responsible veterinarian in lactating bitches and queens.

3.8 Interaction with other medicinal products and other forms of interaction

Phenytoin, barbiturates, ephedrine and rifampicin may accelerate the metabolic clearance of corticosteroids resulting in decreased blood levels and reduced physiological effect.
The concomitant use of this veterinary medicinal product with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.
Administration of prednisolone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypokalaemia may be increased if prednisolone is administered together with potassium depleting diuretics.
Precautions need to be taken when combining use with insulin.
Treatment with the veterinary medicinal product may interfere with vaccination efficacy. When vaccinating with attenuated live vaccines, a two week interval should be observed before or after treatment.

3.9 Administration routes and dosage

Oral use.
The dose and total duration of treatment, among the authorized posology range, is determined by the veterinarian per individual case depending on the severity of symptoms.

Starting dose for dogs and cats: 0.5 - 2.0 mg per kg bodyweight per day.

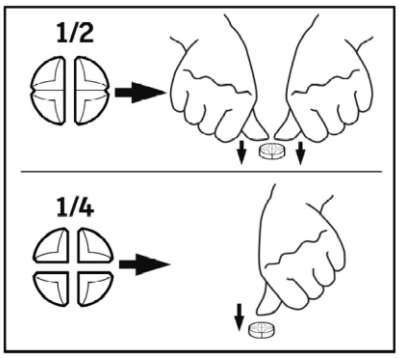
Treatment for one to three weeks at the above dosage levels may be required. For longer term treatment: when after a period of daily dosing the desired effect has been achieved, the dose should be reduced until the lowest effective dose is reached. The reduction of the dose should be made by alternate day therapy and /or by halving the dose with intervals of 5-7 days until the lowest effective dose is reached. Dogs should be dosed in the morning and cats should be dosed in the evening to coincide with the endogenous cortisol peak.

The following table is intended as a guide to dispensing the veterinary medicinal product at the minimum dose of 0.5 mg/kg bw and the maximum dose of 2 mg/kg bw:

	Number of tablets	
	Hedylon 5 mg for dogs and cats	
Body weight (kg)	**Minimum dose 0.5 mg/kg bw**	**Maximum dose 2 mg/kg bw**
≤ 2.5 kg	¼	1
> 2.5 - 5 kg	½	1-2
> 5 - 7.5 kg	¾	2-3
> 7.5 - 10 kg	1	3-4
> 10 - 12.5 kg	1 ¼	4-5
> 12.5 - 15 kg	1 ½	5-6
> 15 – 17.5 kg	1 ¾	6-7
> 17.5 - 20 kg	2	7-8

 = ¼ Tablet  = ½ Tablet  = ¾ Tablet  = 1 Tablet

Tablets can be divided into 2 or 4 equal parts to ensure accurate dosing.



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

An overdose will not cause other effects than those stated in section 3.6.
There is no specific antidote. Signs of overdosage should be treated symptomatically.

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 :

QH02AB06

4.2 Pharmacodynamics

Prednisolone is a synthetic corticosteroid anti-inflammatory drug belonging to the glucocorticoid family. The main effects of prednisolone are the same as those of glucocorticoids:

Anti-inflammatory action:
The anti-inflammatory properties of prednisolone are expressed at a low dose and are explained by:
- the inhibition of phospholipase A2, which reduces the synthesis of arachidonic acid, a precursor of many proinflammatory metabolites. Arachidonic acid is released from the phospholipid component of the cell membrane by the action of phospholipase A2. The corticosteroids indirectly inhibit this enzyme by inducing the endogenous synthesis of polypeptides, lipocortins, which have an anti-phospholipase action;
- by a membrane stabilising effect, particularly in relation to lysosomes, thus preventing enzymes from being released outside the lysosomal compartment.

Immunosuppressive action:
The immunosuppressive properties of prednisolone are expressed at a higher dose on both the macrophages (slower phagocytosis, decreased flow to inflammatory foci) and the neutrophils and lymphocytes. Administration of prednisolone reduces the production of antibodies and inhibits several complement components.

Antiallergic action:
Like all corticosteroids, prednisolone inhibits the release of histamine by mast cells. Prednisolone is active in all manifestations of allergy as a complement to the specific treatment.

4.3 Pharmacokinetics

Prednisolone is readily absorbed from the gastro-intestinal tract. Peak plasma concentrations are reached 0.5 to 1.5 hours after administration in dogs and 0.25 to 2 hours after administration in cats, with a plasma half-life of between 3 and 5 hours in dogs and between 0.5 and 1 hour in cats. It is distributed to all tissues and body fluids, even in the cerebrospinal fluid. It is extensively bound to plasma proteins, is metabolized in the liver and primarily excreted via the kidneys. It is excreted in the urine as free and conjugated metabolites and parent compound. It has a biological half-life of several hours, making it suitable for alternate-day therapy.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Store below 25ºC.
Keep the blister in the outer carton in order to protect from light.
Any unused part-tablet should be returned to the blister and used within 4 days.

5.4 Nature and composition of immediate packaging

Opaque PVC/Aluminium blister

Pack sizes:
Cardboard box containing 1 blister of 10 tablets.
Cardboard box containing 3 blisters of 10 tablets.
Cardboard box containing 5 blisters of 10 tablets.
Cardboard box containing 10 blisters of 10 tablets.
Cardboard box containing 25 blisters of 10 tablets.

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

Industrial Veterinaria, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10509/018/001

8. DATE OF FIRST AUTHORISATION

15/02/2019

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

05/03/2026

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).