Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Hedylon 5 mg tablets for dogs and cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:
Active substance:
Prednisolone 5 mg

Excipients:
For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Tablet.
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.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

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

4.3 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 4.7 and 4.8.

4.4 Special warnings for each target species

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.

4.5 Special precautions for use

Special precautions for use in animals

In cases where a bacterial infection is present the 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 The dosage should be reduced and withdrawn gradually to avoid precipitation of adrenal insufficiency (see section 4.9).
Corticoids such as prednisolone, exacerbate protein catabolism. Consequently, the 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.

4.6 Adverse reactions (frequency and seriousness)

Anti-inflammatory corticosteroids, such as prednisolone, are known to exert a wide range of side effects. Whilst single high doses are generally well tolerated, they may induce severe side-effects in long term use.
The significant dose related cortisol suppression noticed during therapy is a result of effective doses suppressing the hypothalamic-pituitary-adrenal-axis. Following cessation of treatment, signs of adrenal insufficiency can arise and this may render the animal unable to deal adequately with stressful situations.
The significant increase in triglycerides noticed can be a part of possible iatrogenic hyperadrenocorticism (Cushing's disease) involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, increase in body weight, muscle weakness, wastage and osteoporosis may result. Cortisol suppression and an increase in plasma triglycerides is a very common side-effect of medication with corticoids (more than 1 in 10 animals).
Changes in biochemical, haematological and liver parameters probably associated with the use of prednisolone were significant effects noticed on alkaline phosphatase (increase), lactate dehydrogenase (decrease), albumin (increase), eosinophils, lymphocytes (decrease), segmented neutrophils (increase) and serum hepatic enzymes (increase). A decrease in aspartate transaminase is also noticed.
Systemically administered corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long term use. Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis).
Corticosteroid use may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections.
Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
Other adverse reactions that may occur are: inhibition of longitudinal growth of bones; skin atrophy; diabetes mellitus; behavioral disorders (excitation and depression), pancreatitis, decrease in thyroid hormone synthesis; increase in parathyroid hormone synthesis. See also section 4.7.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

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.

Glucocorticoids are excreted in the milk and may result in growth impairment in suckling young animals. Consequently, the product should be used only according to the benefit / risk assessment of the responsible veterinarian in lactating bitches and queens.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

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.

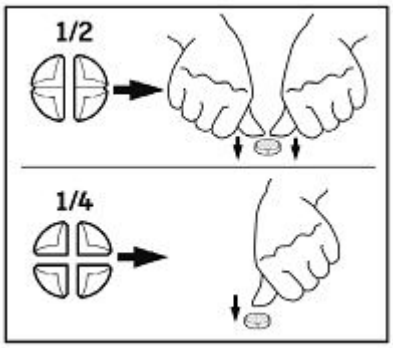
Starting dose for dogs and cats: 0.5 - 2.0 mg per kg bodyweight per day.

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 at night to coincide with the endogenous cortisol peak.

The following table is intended as a guide to dispensing the 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

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



4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

An overdose will not cause other effects than those stated in section 4.6.
There is no specific antidote. Signs of overdosage should be treated symptomatically.

4.11 Withdrawal period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroid for systemic use, Glucocorticoids, Prednisolone.
ATCvet code: QH02AB06.

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Maize starch
Pre-gelatinised starch
Colloidal anhydrous silica
Talc
Magnesium stearate

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Any unused part-tablet should be returned to the blister and used within 4 days.

6.4 Special precautions for storage

Keep the blister in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Opaque PVC/Aluminium blister
Pack sizes:
Cardboard box of 1, 3, 5, 10, or 25 blisters of 10 tablets.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola des Vallès
Barcelona
E-08950
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10425/009/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 February 2019

10 DATE OF REVISION OF THE TEXT