**ANNEX III**

**LABELLING AND PACKAGE LEAFLET**

# A. LABELLING

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Cardboard box**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hedylon 25 mg tablets for dogs [AT, BG, CY, CZ, DK, EE, ES, FI, FR, DE, EL, HU, IE, IS, IT, LV, LT, NL, NO, PL, PT, RO, SE, SI, SK]
Prednicure 25 mg tablets for dogs [BE]
Prednisolone

## 2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
**Active substance:**
Prednisolone 25 mg

## 3. PHARMACEUTICAL FORM

Tablet

## 4. PACKAGE SIZE

10 tablets
30 tablets
50 tablets
100 tablets
250 tablets

## 5. TARGET SPECIES

Dogs

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD(S)

## 9. SPECIAL WARNING(S), IF NECESSARY

## 10. EXPIRY DATE

EXP {month/year}

## 11. SPECIAL STORAGE CONDITIONS

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.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

## 14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès (Barcelona)
Spain

## 16. MARKETING AUTHORISATION NUMBER(S)

## 17. MANUFACTURER'S BATCH NUMBER

Batch {number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Blisters**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hedylon 25 mg tablets [AT, BG, CY, CZ, DK, EE, ES, FI, FR, DE, EL, HU, IE, IS, IT, LV, LT, NL, NO, PL, PT, RO, SE, SI, SK]
Prednicure 25 mg tablets [BE]

Prednisolone

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

LIVISTO

## 3. EXPIRY DATE

EXP {month/year}

## 4. BATCH NUMBER

Lot {number}

## 5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

# B. PACKAGE LEAFLET

**PACKAGE LEAFLET:**
**Hedylon 25 mg tablets for dogs [AT, BG, CY, CZ, DK, EE, ES, FI, FR, DE, EL, HU, IE, IS, IT, LV, LT, NL, NO, PL, PT, RO, SE, SI, SK]**
**Prednicure 25 mg tablets for dogs [BE]**

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès
(Barcelona), Spain

Manufacturer responsible for batch release:
Industrial Veterinaria, S.A.
Esmeralda, 19
E-08950 Esplugues de Llobregat (Barcelona) Spain

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Hedylon 25 mg tablets for dogs [AT, BG, CY, CZ, DK, EE, ES, FI, FR, DE, EL, HU, IE, IS, IT, LV, LT, NL, NO, PL, PT, RO, SE, SI, SK]
Prednicure 25 mg tablets for dogs [BE]
Prednisolone

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each tablet contains:
Active substance:
Prednisolone 25 mg

White round tablets with a cross-shaped break line on one side and number 25 engraved on the reverse.
Tablets can be divided into 2 or 4 equal parts

## 4. INDICATION(S)

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

## 5. 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 “Pregnancy and lactation” and “Interaction with other medicinal products and other forms of interaction”.

## 6. ADVERSE REACTIONS

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 “Pregnancy and lactation”.

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)

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system {national system details}.

## 7. TARGET SPECIES

Dogs

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

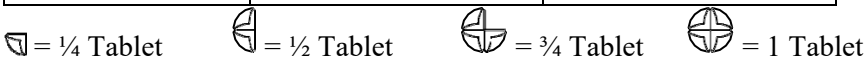
Oral use.
The dose and total duration of treatment, among the authorized posology range, is determined by the veterinarian per individual case depending on the severity of symptoms.

Starting dose: 0.5 - 2.0 mg per kg bodyweight per day.

Administration 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 treated in the morning on account of differences in day rhythm.

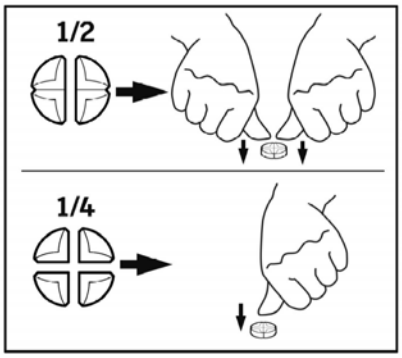
The following table is intended as a guide to dispensing the product at the minimum dose of 0.5 mg/kg bw and the maximum dose of 2 mg/kg bw:

| | **Number of tablets** | |
|---|---|---|
| | **Hedylon 25 mg for dogs** | |
| **Body weight (kg)** | **Minimum dose 0.5 mg/kg bw** | **Maximum dose 2 mg/kg bw** |
| > 10 - 12.5 kg | ¼ | 1 |
| >12.5 - 25 kg | ½ | 1-2 |
| >25 - 37.5 kg | ¾ | 2-3 |
| > 37.5 - 50 kg | 1 | 3-4 |
| > 50 - 62.5 kg | 1 ¼ | 4-5 |
| > 62.5 - 75 kg | 1 ½ | 5-6 |




## 9. ADVICE ON CORRECT ADMINISTRATION

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




## 10. WITHDRAWAL PERIOD(S)

Not applicable

## 11. SPECIAL STORAGE PRECAUTIONS

Store below 25ºC.
Keep out of the sight and reach of children.
Keep the blister in the outer carton in order to protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.
Any unused part-tablet should be returned to the blister and used within 4 days.

## 12. SPECIAL WARNING(S)

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.

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 “Dosage for each species, route and method of administration”).
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 animals 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.

Pregnancy and lactation:
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.

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.

Overdose (symptoms, emergency procedures, antidotes):
An overdose will not cause other effects than those stated in section “Adverse reactions”.
There is no specific antidote. Signs of overdosage should be treated symptomatically.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

## 15. OTHER INFORMATION

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.