1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equisolon 100 mg oral powder for horses
Equisolon 300 mg oral powder for horses
Equisolon 600 mg oral powder for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
100 mg prednisolone per 3 g sachet.
300 mg prednisolone per 9 g sachet
600 mg prednisolone per 18 g sachet

Qualitative composition of excipients and other constituents
Lactose monohydrate
Anise aroma powder
Silica colloidal hydrated

White to off-white powder.

3. CLINICAL INFORMATION

3.1 Target species

Horses.

3.2 Indications for use for each target species

Alleviation of inflammatory and clinical parameters associated with recurrent airway obstruction (RAO) in horses, in combination with environmental control.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.
Do not use in viral infections during the viraemic stage or in cases of systemic mycotic infections.
Do not use in animals suffering from gastrointestinal ulcers.
Do not use in animals suffering from corneal ulcers.
Do not use during pregnancy.

3.4 Special warnings

Corticoid administration is to induce an improvement in clinical signs rather than a cure. The treatment should be combined with environmental control.

Each case should be assessed individually by the veterinarian and an appropriate treatment program determined. Treatment with prednisolone should only be initiated when satisfactory alleviation of clinical symptoms have not been obtained or are unlikely to be obtained by environmental control alone.

Treatment with prednisolone may not sufficiently restore respiratory function in all cases, and in each individual case the use of veterinary medicinal products with more rapid onset of action may need to be considered.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Do not use in animals suffering from diabetes mellitus, renal insufficiency, cardiac insufficiency, hyperadrenocorticism, or osteoporosis.

Use of corticosteroids in horses has been reported to induce laminitis (see section 3.6). Therefore horses should be monitored frequently during the treatment period.

Because of the pharmacological properties of prednisolone, use with caution when the veterinary medicinal product is used in animals with a weakened immune system.

Whilst single high doses of corticosteroids are generally well tolerated, they may induce severe side-effects in long term use. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to corticosteroids or any of the excipients should avoid contact with the veterinary medicinal product.

The veterinary medicinal product should not be administered by pregnant women, due to the risk of foetal malformation.

Personal protective equipment consisting of gloves and protective mask should be worn when handling the veterinary medicinal product.

In order to prevent dust formation, do not shake the veterinary medicinal product.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Adrenal gland disorder[a] Hypocortisolaemia[a] Elevated triglyceride[b]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Laminitis[c] Neurological signs (e.g. Ataxia, Head tilt, Incoordination) Restlessness Recumbency, Anorexia Elevated serum alkaline phosphatase (ALP)[d] Gastric ulceration[e], Colic, Intestinal disorder[e] Excessive sweating Urticaria

[a] Result of effective doses suppressing the hypothalamo-pituitreal adrenal axis. Following cessation of treatment, signs of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations.

[b] This can be a part of possible iatrogenic hyperadrenocorticism (Cushings disease) involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, increase in body weight, muscle weakness and wastage and osteoporosis may result.

[c] Horses should be monitored frequently during the treatment period.

[d] Could be related to enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

[e] Gastrointestinal ulceration may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma (see section 3.3).

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 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

The safety of the veterinary medicinal product has not been established during pregnancy.

Pregnancy:
Do not use (during the whole or part of the pregnancy).
Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals.
Administration in late pregnancy is likely to cause abortion or early parturition in ruminants and may have a similar effect in other species.

3.8 Interaction with other medicinal products and other forms of interaction

The concomitant use of this veterinary medicinal product with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration. Because corticosteroids can reduce the immunoresponse to vaccination, prednisolone should not be used in combination with vaccines or within two weeks after vaccination.

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.

3.9 Administration routes and dosage

Oral use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

A single dose of 1 mg prednisolone/kg body weight per day corresponds to 100 mg prednisolone in a 3 g sachet per 100 kg body weight (see dosing table below).
Treatment may be repeated at 24 hour intervals during 10 consecutive days.
The correct dose should be mixed into a small amount of food.
Food mixed with the veterinary medicinal product should be replaced if not consumed within 24 hours.

Sachets of different pack size can be combined to achieve the correct dose, as per the table below:

Bodyweight (kg) of horse	**Number of sachets**		
	100 mg prednisolone (3 g sachet)	**300 mg prednisolone (9 g sachet)**	**600 mg prednisolone (18 g sachet)**
100-200	2		

200-300		1	
300-400	1	1	
400-500	2	1	
500-600			1
600-700	1		1
700-800	2		1
800-900		1	1
900-1000	1	1	1

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

Short-term administration of even large doses is unlikely to cause serious harmful systemic effects. However, long term use of corticosteroids may lead to serious adverse events (please see section 3.6).

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

Meat and offal: 10 days.
Not authorised for use in mares producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH02AB06

4.2 Pharmacodynamics

Prednisolone is an intermediate acting corticosteroid having about 4 times the anti-inflammatory activity and about 0.8 times the sodium-retaining effect of cortisol. Corticosteroids suppress the immunologic response by inhibition of dilatation of capillaries, migration and function of leucocytes and phagocytosis. Glucocorticoids have an effect on metabolism by increasing gluconeogenesis.

Recurrent airway obstruction (RAO) is a commonly occurring respiratory disease in mature horses. Affected horses are susceptible to inhaled antigens and other pro-inflammatory agents, including fungal spores and dust-derived endotoxin. Where medical treatment of horses with RAO is required, glucocorticoids are effective in controlling clinical signs and decreasing neutrophilia in airways.

4.3 Pharmacokinetics

Following oral administration in horses prednisolone is readily absorbed giving a prompt response which is maintained for approximately 24 hours. The overall average t_{max} is 2.5 ± 3.1 hours, C_{max} is 237 ± 154 ng/ml and AUC_t is 989 ± 234 ng·h/ml. $t_{½}$ is 3.1 ± 2.3 hours but is not meaningful from a therapy standpoint when evaluating systemic corticosteroids.

Bioavailability after oral administration is about 60%. Partial metabolism of prednisolone to the biologically inert substance prednisone takes place. Equal amounts of prednisolone, prednisone, 20β-dihydroprednisolone and 20β-dihydroprednisone are found in urine. Excretion of prednisolone is complete within 3 days.

Multiple dosing does not result in plasma accumulation of prednisolone.

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: 3 years.
Shelf life after incorporation into meal or pelleted feed: 24 hours.

5.3 Special precautions for storage

Opened sachets should not be stored.

5.4 Nature and composition of immediate packaging

Pentalaminate sachets (inner coating LDPE).

Pack sizes:
Cardboard box with 20 single use sachets of 3 g oral powder (containing 100 mg prednisolone)
Cardboard box with 10 single use sachets of 9 g oral powder (containing 300 mg prednisolone)
Cardboard box with 10 single use sachets of 18 g oral powder (containing 600 mg prednisolone)

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

Le Vet B.V.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/161/001-003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 12/03/2014

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

{MM/YYYY}