

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equisolon 33 mg/g oral powder for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Jar with 180 g or 504 g oral powder. One gram contains:

Active substance:

prednisolone 33.3 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral powder.

White to off-white powder

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not use in known 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.

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 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 medicinal products with more rapid onset of action may need to be considered.

4.5 Special precautions for use

Special precautions for use in animals

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 4.6). 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.

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 must not be in contact with the veterinary medicinal product.

Due to the risk of foetal malformation, the veterinary medicinal product must not be administered by pregnant women.

It is recommended to wear gloves and a protective respiratory mask during the handling and administration of the veterinary medicinal product.

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

4.6 Adverse reactions (frequency and seriousness)

Very rarely, laminitis has been observed after use of the product. Therefore horses should be monitored frequently during the treatment period.

Very rarely, neurological signs such as ataxia, recumbency, head tilting, restlessness or incoordination have been observed after use of the product.

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.

The significant dose related cortisol suppression very commonly noticed during therapy is a result of effective doses suppressing the hypothalamo-pituitary-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.

A significant increase in triglycerids occurs very commonly. 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.

An increase of alkaline phosphatase by glucocorticoids is very rarely observed and could be related to enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

Gastrointestinal ulceration has been very rarely reported and gastrointestinal ulceration may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma (see section 4.3). Other gastrointestinal symptoms that have been very rarely observed are colic and anorexia.

Excessive sweating has been very rarely observed. Very rarely urticaria has been observed.

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

The safety of the veterinary medicinal product has not been established in horses during pregnancy, and the product is contraindicated for use in pregnant horses (please see section 4.3).

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.

4.8 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.

4.9 Amounts to be administered and administration route

Oral use.

To ensure administration of the correct dose, body weight should be determined as accurately as possible to avoid under- or overdosing.

A single dose of 1 mg prednisolone/kg body weight per day corresponds to 3 g powder 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.

Using the measuring spoon the following dosing table applies:

Bodyweight (kg) of horse	Jar with measuring spoon (1 spoon = 4.6 g powder)
	Number of spoons
150-300	2
300-450	3
450-600	4
600-750	6
750-1000	7

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

Short-term administration of even large doses is unlikely to cause serious harmful systemic effects. However, chronic usage of corticosteroids may lead to serious adverse effects (please see section 4.6).

4.11 Withdrawal period(s)

Meat and offal: 10 days.

Not authorised for use in mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: corticosteroid for systemic use, glucocorticoid.

ATCvet code: QH02AB06

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

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. $T_{1/2}$ 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, 20 β -dihydroprednisolone and 20 β -dihydroprednisone are found in urine. Excretion of prednisolone is complete within 3 days.

Multiple dosing does not result in plasma accumulation of prednisolone.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate
Anise aroma powder
Silica colloidal hydrated.

6.2 Major incompatibilities

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

6.3 Shelf life

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

Shelf life after first opening the container: 4 weeks.

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

6.4 Special precautions for storage

Store in the original container.

Keep the jar tightly closed.

6.5 Nature and composition of immediate packaging

Cardboard box containing one HDPE (white) jar with LDPE tear band lid containing 180 gram or 504 gram of oral powder and one polystyrene (colourless) measuring spoon (measuring 4.6 grams of oral powder).

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
THE NETHERLANDS

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/161/004
EU/2/14/161/005

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 12/03/2014
Date of last renewal: 05/02/2019

10. DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency <http://www.ema.europa.eu/>.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.