PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX - Sachets}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equisolon 600 mg oral powder for horses

2. STATEMENT OF ACTIVE SUBSTANCES

600 mg prednisolone per 18 g sachet

3. PACKAGE SIZE

10 x 18 g

4. TARGET SPECIES

Horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once the veterinary medicinal product has been incorporated into a meal or pelleted feed, use within 24 hours.

9. SPECIAL STORAGE PRECAUTIONS

Opened sachets should not be stored.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 19994/5003

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {Sachet 18 gram}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equisolon

Horses

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

600 mg prednisolone per 18 g sachet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once the veterinary medicinal product has been incorporated into a meal or pelleted feed, use within 24 hours.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

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. Composition

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

White to off-white powder.

3. Target species

Horses.

4. Indications for use

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

5. 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.

6. Special warnings

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.

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 severe lameness of (especially) the front hooves (see the section “Adverse events”). 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.

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

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.

Overdose:
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 the section “Adverse events”).

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

7. 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 ‘Contraindications’).

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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

9. Advice on correct administration

Food mixed with the veterinary medicinal product should be replaced if not consumed within 24 hours.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and the carton after Exp. The expiry date refers to the last day of that month.
Opened sachets should not be stored.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Equisolon 100 mg oral powder for horses	Vm 19994/5000
Equisolon 300 mg oral powder for horses	Vm 19994/5001
Equisolon 600 mg oral powder for horses	Vm 19994/5003

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
Netherlands
Tel.: +31 348 563 434

Manufacturer responsible for batch release:
LelyPharma B.V.
Zuiveringweg 42
8243 PZ Lelystad
Netherlands

Local representatives and contact details to report suspected adverse reactions:
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel: +44 (0) 1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Approved 03 December 2025
Gavin Hall