ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX - Sachets

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
prednisolone

2. STATEMENT OF ACTIVE SUBSTANCES

100 mg prednisolone
300 mg prednisolone
600 mg prednisolone

3. PHARMACEUTICAL FORM

Oral powder.

4. PACKAGE SIZE

20 x 3 g
10 x 9 g
10 x 18 g

5. TARGET SPECIES

Horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.

8. WITHDRAWAL PERIOD

Withdrawal period:

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

9. SPECIAL WARNING(S), IF NECESSARY

It is recommended to wear gloves and a protective respiratory mask during the handling and administration of the product. In order to prevent dust formation, do not shake the veterinary medicinal product.
Read the package leaflet before use.

10. EXPIRY DATE

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

11. SPECIAL STORAGE CONDITIONS

Opened sachets should not be stored.

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

Disposal: read package leaflet.

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 REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/14/161/001-003

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

SACHETS (3, 9 and 18 gram)

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
prednisolone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet B.V.

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Batch {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

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

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

Marketing authorisation holder:
Le Vet B.V.
Wilgenweg 7
3421 TV Oudewater
THE NETHERLANDS

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

2. 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
prednisolone

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

White to off-white powder containing 33.3 mg/g of prednisolone.

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

4. INDICATION(S)

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 known cases of hypersensitivity to the active substance, to corticosteroids and to any other ingredient of the product.

Do not use in viral infections in which the virus particles circulate in the bloodstream or in cases of systemic fungal 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. ADVERSE REACTIONS

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-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.
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 Contraindications). 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 reactions)
- 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.

7. TARGET SPECIES

Horses.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

Oral use.
To ensure a correct dosage body weight should be determined as accurately as possible to avoid under- and overdosing.

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.

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 PERIOD(S)

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.

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

Opened sachets should not be stored.

12. SPECIAL WARNING(S)

Special warnings for the 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.

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 severe lameness of (especially) the front hooves (see section Adverse reactions). 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 mask during handling and administration of the product.
In order to prevent dust formation, do not shake the veterinary medicinal product.

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

Overdose (symptoms, emergency procedures, antidotes)
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 Adverse reactions).

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.

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

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 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

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

15. OTHER INFORMATION

Package (size)
Cardboard box containing 20 pentalaminate sachets (inner coating LDPE) of 3 g (containing 100 mg prednisolone), or 10 sachets of 9 g (300 mg) or 18 g (600 mg) of oral powder.

Not all pack sizes may be marketed.