ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

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

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 mask during handling and administration of the 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-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 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 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

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. $T_{½}$ 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.

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
Sachets are for single use and should be disposed after use/opening.
Shelf life after incorporation into meal or pelleted feed: 24 hours

6.4 Special precautions for storage

Opened sachets should not be stored.

6.5 Nature and composition of immediate packaging

Cardboard box containing 20 pentalaminate sachets (inner coating LDPE) of 3 g (containing 100 mg prednisolone), or 10 sachets of 9 g (containing 300 mg prednisolone) or 18 g (containing 600 mg prednisolone) 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/2/14/161/001-003

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.emea.europa.eu/.

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

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-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 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 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. $T_{½}$ 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.

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.

ANNEX II

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

A. MANUFACTURER RESPONSIBLE FOR BATCH RELEASE

Name and address of the manufacturer responsible for batch release
LelyPharma B.V.
Zuiveringweg 42
8203 AA Lelystad
THE NETHERLANDS

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substance in Equisolon is an allowed substance as described in table 1 of the annex to Commission Regulation (EU) No 37/2010:

Pharmacologically active substance	Marker residue	Animal species	MRL	Target tissues	Other provisions	Therapeutic classification
Prednisolone	Prednisolone	Equidae	4 µg/kg 8 µg/kg 6 µg/kg 15 µg/kg	Muscle Fat Liver Kidney	NO ENTRY	Corticoids/ Glucocorticoids

The excipients listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required, or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

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(S)

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.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX - Jar

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equisolon 33 mg/g oral powder for horses
prednisolone

2. STATEMENT OF ACTIVE SUBSTANCES

33.3 mg/g prednisolone.

3. PHARMACEUTICAL FORM

Oral powder.

4. PACKAGE SIZE

1 jar of 180 g
1 jar of 504 g.
A measuring spoon is included.

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(S)

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 {month/year}
Once opened, use within 4 weeks.
Food mixed with the veterinary medicinal product should be replaced if not consumed within 24 hours.

11. SPECIAL STORAGE CONDITIONS

Store in the original container.
Keep the container tightly closed.

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 SIGHT AND REACH 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/2/14/161/004
EU/2/14/161/005

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Jar

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equisolon 33 mg/g oral powder for horses
prednisolone

2. STATEMENT OF ACTIVE SUBSTANCES

33.3 mg/g prednisolone.

3. PHARMACEUTICAL FORM

Oral powder.

4. PACKAGE SIZE

180 g
504 g

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

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
Once opened, use within 4 weeks.
Food mixed with the veterinary medicinal product should be replaced if not consumed within 24 hours.

11. SPECIAL STORAGE CONDITIONS

Store in the original container. Keep the container tightly closed.

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 SIGHT AND REACH 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/2/14/161/004
EU/2/14/161/005

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

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(S) AND OTHER INGREDIENT(S)

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 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.

7. TARGET SPECIES

Horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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.

PACKAGE LEAFLET
Equisolon 33 mg/g 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 33 mg/g oral powder for horses
Prednisolone

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

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

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 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.

7. TARGET SPECIES

Horses.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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 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.

Using the jar and 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

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.

Store in the original container.
Keep the container tightly closed.
Shelf-life after first opening of the container: 4 weeks.

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 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 respiratory mask during the handling and administration of the product.
In order to prevent dust formation, do not shake the veterinary medicinal product.

Use during pregnancy and lactation
The safety of the veterinary medicinal product during pregnancy has not been established in horses during pregnancy, 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 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 gram of oral powder).
Not all pack sizes may be marketed.