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 (3 g sachet)
300 mg prednisolone (9 g sachet)
600 mg prednisolone (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

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 medication with more rapid onset of action may need to be considered.
4.5 Special precautions for use

Special precautions for use in animals
Except in emergency situations, 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. Therefore horses should be monitored frequently during the treatment period.
Because of the pharmacological properties of prednisolone, special care should be taken 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 prednisolone or any of the excipients should avoid contact with the veterinary medicinal product.
Due to the risk of foetal malformation, the veterinary medicinal product should not be administered by pregnant women.
In order to prevent dust formation, do not shake the veterinary medicinal product.

4.6 Adverse reactions (frequency and seriousness)

Anti-inflammatory corticosteroids, such as prednisolone, are known to exert a wide range of side effects. Whilst single high doses 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 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. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment.
The significant increase in triglycerids noticed 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.
The increase of alkaline phosphatase by glucocorticoids could be related to enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.
Other changes in blood biochemical and haematological parameters probably associated with the use of prednisolone were significant effects noticed on lactate dehydrogenase (decrease) and albumin (increase) and on eosinophils, lymphocytes (decrease) and segmented neutrophils (increase).
A decrease in aspartate transaminase is also noticed.
Systemically administered corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long term use. Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis).
Corticosteroid use may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.
Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

Endocrine and metabolic
Very common: Cortisol suppression and an increase in plasma tryglicerids.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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 should not be used during 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.

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

For 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 corresponding to 3 g powder per 100 kg body weight.
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, e.g.:

<table>
<thead>
<tr>
<th>Bodyweight (kg) of horse</th>
<th>100 mg (100 kg bodyweight)</th>
<th>300 mg (300 kg bodyweight)</th>
<th>600 mg (600 kg bodyweight)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100-200</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>200-300</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>300-400</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>400-500</td>
<td>2</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>500-600</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>600-700</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>700-800</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>800-900</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>900-1000</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>
4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

An overdose can induce drowsiness in horses

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 $T_{\text{max}}$ is 2.5 ± 3.1 hours, $C_{\text{max}}$ 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, 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 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: 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 pentalamine 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
tel: +31 (0)348565858
fax: +31 (0)348565454
e-mail: Info@levetpharma.com

8. **MARKETING AUTHORISATION NUMBER(S)**

EU/2/14/161/001-003

9. **DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

12/03/2014

10 **DATE OF REVISION OF THE TEXT**


**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

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

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 medication with more rapid onset of action may need to be considered.
4.5 Special precautions for use

Special precautions for use in animals
Except in emergency situations, 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. Therefore horses should be monitored frequently during the treatment period.
Because of the pharmacological properties of prednisolone, special care should be taken 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 prednisolone or any of the excipients should avoid contact with the veterinary medicinal product.
Due to the risk of foetal malformation, the veterinary medicinal product should not be administered by pregnant women.

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

4.6 Adverse reactions (frequency and seriousness)

Anti-inflammatory corticosteroids, such as prednisolone, are known to exert a wide range of side effects. Whilst single high doses 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 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. Consideration should therefore be given to means of minimising the withdrawal of treatment.
The significant increase in triglycerids noticed can be a part of possible iatrogenic hyperadrenocorticism (Cushing’s 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.
The increase of alkaline phosphatase by glucocorticoids could be related to enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes. Other changes in blood biochemical and haematological parameters probably associated with the use of prednisolone were significant effects noticed on lactate dehydrogenase (decrease) and albumin (increase) and on eosinophils, lymphocytes (decrease) and segmented neutrophils (increase). A decrease in aspartate transaminase is also noticed.
Systemically administered corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long term use. Systemic corticosteroids have caused deposition of calcium in the skin (calciosis cutis).
Corticosteroid use may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.
Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

Endocrine and metabolic
Very common: Cortisol suppression and an increase in plasma tryglicerids.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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 should not be used during 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.

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

For 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 corresponding to 3 g powder per 100 kg body weight. 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:

<table>
<thead>
<tr>
<th>Bodyweight (kg) of horse</th>
<th>Jar with measuring spoon (= 4.6 g powder)</th>
<th>Number of spoons</th>
</tr>
</thead>
<tbody>
<tr>
<td>150-300</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>300-450</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>450-600</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>600-750</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>750-1000</td>
<td>7</td>
<td></td>
</tr>
</tbody>
</table>

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

An overdose can induce drowsiness in horses.
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 $T_{\text{max}}$ is $2.5 \pm 3.1$ hours, $C_{\text{max}}$ is $237 \pm 154$ ng/ml and AUC is $989 \pm 234$ ng∙h/ml. $T_{\frac{1}{2}}$ is $3.1 \pm 2.3$ 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 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: 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.

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
tel: +31 (0)348565858
fax: +31 (0)348565454
e-mail:Info@levetpharma.com

8. MARKETING AUTHORISATION NUMBER(S)

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

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12/03/2014

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.
Zuiveringsweg 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:

<table>
<thead>
<tr>
<th>Pharmacologically active substance</th>
<th>Marker residue</th>
<th>Animal species</th>
<th>MRL</th>
<th>Target tissues</th>
<th>Other provisions</th>
<th>Therapeutic classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prednisolone</td>
<td>Prednisolone</td>
<td>Equidae</td>
<td>4 μg/kg</td>
<td>Muscle Fat Liver Kidney</td>
<td>NO ENTRY</td>
<td>Corticoids/ Glucocorticoids</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>8 μg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6 μg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>15 μg/kg</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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
### 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 AND OTHER 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**

   For oral use.  
   Read the package leaflet before 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

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. BATCH NUMBER**

Batch {number}

**4. EXPIRY DATE**

EXP

**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 AND OTHER SUBSTANCES**

   33.3 mg/g prednisolone.

3. **PHARMACEUTICAL FORM**

   Oral powder.

4. **PACKAGE SIZE**

   180 g
   504 g
   A measuring spoon is included.

5. **TARGET SPECIES**

   Horses.

6. **INDICATION(S)**

7. **METHOD AND ROUTE(S) OF ADMINISTRATION**

   For oral use;
   Read the package leaflet before 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**
Read the package leaflet before use.

10. EXPIRY DATE

EXP  {month/year}
Once opened, use by 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 AND OTHER 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**

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

9. **SPECIAL WARNING(S), IF NECESSARY**

   Read the package leaflet before use.
### 10. EXPIRY DATE

EXP
Once opened, use by 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 AUTHORIZATION NUMBER(S)

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

### 17. MANUFACTURER’S BATCH NUMBER

Batch {number}
B. PACKAGE LEAFLET
1. **NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

   Marketing authorisation holder:
   Name: Le Vet B.V.
   Address: Wilgenweg 7
            3421 TV Oudewater
            The Netherlands

   Manufacturer for the batch release:
   Name: LelyPharma B.V.
   Address: Zuiveringsweg 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.

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

Anti-inflammatory corticosteroids, such as prednisolone, are known to exert a wide range of side effects. Whilst single high doses 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 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. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment.

The significant increase in triglycerids noticed 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.

The increase of alkaline phosphatase by glucocorticoids could be related to enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

Other changes in blood biochemical and haematological parameters probably associated with the use of prednisolone were significant effects noticed on lactate dehydrogenase (decrease) and abumin (increase) and on eosinophils, lymphocytes (decrease) and segmented neutrophils (increase). A decrease in aspartate transaminase is also noticed.

Systemically administered corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long term use. Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis).

Corticosteroid use may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.

Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

Endocrine and metabolic

Very common: Cortisol suppression and an increase in plasma tryglicerids.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

For 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 corresponding to 3 g powder per 100 kg body weight.
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**
Sachets of different pack size can be combined to achieve the correct dose, e.g.:

<table>
<thead>
<tr>
<th>Bodyweight (kg) of horse</th>
<th>100 mg (100 kg bodyweight)</th>
<th>300 mg (300 kg bodyweight)</th>
<th>600 mg (600 kg bodyweight)</th>
</tr>
</thead>
<tbody>
<tr>
<td>100-200</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>200-300</td>
<td></td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>300-400</td>
<td>1</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>400-500</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>500-600</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>600-700</td>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>700-800</td>
<td>2</td>
<td></td>
<td></td>
</tr>
<tr>
<td>800-900</td>
<td></td>
<td></td>
<td>1</td>
</tr>
<tr>
<td>900-1000</td>
<td>1</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

9. **ADVICE ON CORRECT ADMINISTRATION**
Food mixed with the veterinary medicinal product should be replaced if not consumed within 24 hours.

10. **WITHDRAWAL PERIOD**
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 medication with more rapid onset of action may need to be considered.

**Special precautions for use in animals**
Except in emergency situations, 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. Therefore horses should be monitored frequently during the treatment period. Because of the pharmacological properties of prednisolone, special care should be taken 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 prednisolone or any of the excipients should avoid contact with the veterinary medicinal product. Due to the risk of foetal malformation, the veterinary medicinal product should not be administered by pregnant women. 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. 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)(if necessary)**
An overdose can induce drowsiness in horses.

**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.

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**

15. **OTHER INFORMATION**

Package (size)
Cardboard box containing 20 pentalamine sachets (inner coating LDPE) of 3 g (containing 100 mg prednisolone), or 10 sachets of 9 g (200 mg) or 18 g (300 mg) of oral powder.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.
España
Boehringer Ingelheim España, S.A.
Prat de la Riba, 50
08174 Sant Cugat del Vallès (Barcelona)
Tel: +34 93 404 51 00

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Agro-Pecuários, S.A.
Centro Empresarial da Rainha, Lote 27
2050-501 Vila Nova da Rainha
Tel: +351 - 263 406 570

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Télécopie : +33 03 26 50 47 43
infoveto@rei.boehringer-ingleheim.com

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SE-201 24 Malmö
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Lietuva
Boehringer Ingelheim
RCV GmbH & Co KG

United Kingdom
Boehringer Ingelheim Limited,
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Bracknell, Berkshire, RG12 8YS,
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Republika Hrvatska
Boehringer Ingelheim
RCV GmbH & Co KG
1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Name: Le Vet B.V.
Address: Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer for the batch release:
Name: LelyPharma B.V.
Address: Zuiveringsweg 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 AND OTHER INGREDIENTS

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

The significant dose related cortisol suppression 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. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment.

The significant increase in triglycerids noticed can be a part of possible iatrogenic hyperadrenocorticism (Cushing’s 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.

The increase of alkaline phosphatase by glucocorticoids could be related to enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

Other changes in blood biochemical and haematological parameters probably associated with the use of prednisolone were significant effects noticed on lactate dehydrogenase (decrease) and albumin (increase) and on eosinophils, lymphocytes (decrease) and segmented neutrophils (increase).

A decrease in aspartate transaminase is also noticed.

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Corticosteroid use may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.

Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

Endocrine and metabolic
Very common: Cortisol suppression and an increase in plasma tryglicerids.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
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- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses.

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

For 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 corresponding to 3 g powder per 100 kg body weight.

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:
<table>
<thead>
<tr>
<th>Bodyweight (kg) of horse</th>
<th>Jar with measuring spoon (= 4.6 g powder)</th>
<th>Number of spoons</th>
</tr>
</thead>
<tbody>
<tr>
<td>150-300</td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>300-450</td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>450-600</td>
<td></td>
<td>4</td>
</tr>
<tr>
<td>600-750</td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>750-1000</td>
<td></td>
<td>7</td>
</tr>
</tbody>
</table>

9. **ADVICE ON CORRECT ADMINISTRATION**

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

10. **WITHDRAWAL PERIOD**

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

Special precautions for use in animals
Except in emergency situations, 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. Therefore horses should be monitored frequently during the treatment period.
Because of the pharmacological properties of prednisolone, special care should be taken 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 the prednisolone or any of the excipients should avoid contact with the veterinary medicinal product.
Due to the risk of foetal malformation, the veterinary medicinal product should not be administered by pregnant women.
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 should not be used during 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.

Overdose (symptoms, emergency procedures, antidotes) (if necessary)
An overdose can induce drowsiness in horses.

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.

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

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.
Not all pack sizes may be marketed.

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


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