ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipred 50 mg tablets for horses
Prednisolone

2. STATEMENT OF ACTIVE SUBSTANCES

1 tablet contains 50 mg prednisolone

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

50 tablets
100 tablets
200 tablets

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 (S)

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

9. SPECIAL WARNING(S), IF NECESSARY

Harmful after ingestion, especially by young children. Store in a closed cabinet. Return any divided tablet to the opened blister. Read the package leaflet before use.

10. EXPIRY DATE

EXP <month/year>
Shelf life of divided tablets: 3 days.

11. SPECIAL STORAGE CONDITIONS

Return any divided tablet to the opened blister.

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

Read the package leaflet before use.

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

CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 20916/4026

17. MANUFACTURER'S BATCH NUMBER

Batch <number>

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipred 50 mg tablets for horses
Prednisolone

2. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsges. mbH

3. EXPIRY DATE

EXP <month/year>

4. BATCH NUMBER

Batch <number>

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Equipred 50 mg tablets 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 and manufacturer responsible for batch release:
CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipred 50 mg tablets for horses
Prednisolone

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

1 tablet contains:

Active substance:
Prednisolone: 50 mg

White, convex tablet embossed with “50”.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.
Do not use in viral infections in which the virus particles circulate in the bloodstream or in cases of mycotic infections.
Do not use in animals suffering from gastrointestinal ulcers.
Do not use in animals suffering from corneal ulcers.
Do not use during pregnancy.

6. 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.

The significant dose related cortisol suppression very commonly noticed during therapy is a result of effective doses suppressing the hypothalamic -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.
The significant increase in triglycerides occurs very commonly. This may result in a 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.
The 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.
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

For oral use.
The product should be mixed in small amount of feed.
To ensure administration of the correct dose, body weight should be determined as accurately as possible to avoid under- or overdosing. Tablets may be divided along score lines to facilitate accurate dosing.
A single dose of 1 mg prednisolone/kg body weight per day corresponding to 2 tablets per 100 kg body weight.
Treatment may be repeated at 24 hour intervals during 10 consecutive days.

9. ADVICE ON CORRECT ADMINISTRATION

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.
This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and blister after EXP.
If the tablets are divided, the remaining parts should be kept in the blister pack. Any divided tablets remaining after 3 days should be discarded.

12. SPECIAL WARNING(S)

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 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.
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. 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:
This product may cause allergic reactions. People with known hypersensitivity to prednisolone or other corticosteroids, or any of the excipients should avoid contact with the veterinary medicinal product.
This product may be irritating to the eyes. Avoid hand-to-eye contact. In case of contact with eyes, rinse with plenty of water. If irritation persists, seek medical attention.
This product may cause adverse effects after ingestion. Do not eat or drink when handling the product. Unused tablet parts should be placed back into the blister and carton and carefully kept away from children. Store in a closed cabinet. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after handling the tablets.
Corticosteroids can cause foetal malformation; therefore, it is recommended that pregnant women avoid contact with the veterinary medicinal product.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in horses during pregnancy and lactation.
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.
Do not use during pregnancy (see contraindications).
Lactation:
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interactions 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 immune response to vaccination, prednisolone should not be used in combination with vaccines or within two weeks after vaccination.
Administration of prednisolone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypokalaemia may be increased if prednisolone is administered together with potassium depleting diuretics.

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

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 or pharmacist 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

The blisters are available in cartons of 50, 100 or 200 tablets.
Not all pack sizes may be marketed.

Approved 18 November 2019