# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipred 50 mg tablets for horses

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains:

**Active substance:**

50 mg prednisolone

For the full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Tablet.
White, convex tablet embossed with “50”.
The tablet can be divided into halves and quarters.

## 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 – severe asthma) in horses, in combination with environmental control.

### 4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.
Do not use in viral infections during the viraemic stage or in cases of 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 (see section 4.7)

### 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 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.
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 the 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 the eyes, rinse with plenty of water. If irritation persists, seek medical attention.
This product may cause adverse effects after ingestion. Avoid hand-to-mouth contact. 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.

## 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.

The significant dose related cortisol suppression very commonly noticed during therapy is a result of effective doses suppressing the hypothalamic-pituitaryadrenal 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).

## 4.7 Use during pregnancy, lactation or lay

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 section 4.3)
Lactation
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

## 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 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.

## 4.9 Amounts to be administered and administration route

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.

## 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, prednisolone.
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 immune response by inhibition of dilatation of capillaries, migration and function of leucocytes and phagocytosis. Glucocorticoids have an effect on metabolism by increasing gluconeogenesis.
Where medical treatment of horses with RAO (severe asthma) 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. $T_{1/2}$ is 3.1 ± 2.3 hours.
Bioavailability after oral administration is about 60%. Partial metabolism of prednisolone to the biologically inert substance prednisone takes place. Equal amounts of prednisolone, prednisone, 20**β**-dihydroprednisolone and 20**β**-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
Cellulose
Silica, colloidal anhydrous
Croscarmellose sodium
Sodium starch glycolate
Magnesium stearate

### 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 of divided tablets after first opening the immediate packaging: 3 days.

### 6.4 Special precautions for storage

This veterinary medicinal product does not require any special temperature storage conditions.
Return any divided tablet to the opened blister.

### 6.5 Nature and composition of immediate packaging

PVC/PVDC/Alu blisters containing 10 tablets.
The blisters are available in cartons of 50, 100 or 200 tablets.

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

CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

## 8. MARKETING AUTHORISATION NUMBER

Vm 20916/4026

## 9. DATE OF FIRST AUTHORISATION

18 November 2019

## 10. DATE OF REVISION OF THE TEXT

18 November 2019

Approved 18 November 2019