1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipred 50 mg tablets for horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substances:

50 mg prednisolone

Excipients:

Qualitative composition of excipients and other constituents
Lactose monohydrate
Cellulose
Silica, colloidal anhydrous
Croscarmellose sodium
Sodium starch glycolate
Magnesium stearate

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

3. CLINICAL INFORMATION

3.1 Target species

Horses

3.2 Indications for use for each target species

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

3.3 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 3.7)

3.4 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 has not been obtained or is 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product may cause adverse effects after ingestion. Avoid hand-to-mouth contact. Do not eat or drink when handling the veterinary medicinal 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.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Hypocortisolaemia[1] Adrenal gland disorder[1] Elevated triglyceride[2]
Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Laminitis[3] Neurological signs (e.g. Ataxia, Head tilt, Incoordination) Restlessness Recumbency, Anorexia Elevated serum alkaline phosphatase (ALP)[4] Gastrointestinal ulceration[5], Colic, Excessive sweating Urticaria

[1] 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.
[2] 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.
[3] Horses should be monitored frequently during the treatment period.
[4] Could be related to enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.
[5] Gastrointestinal ulceration may be exacerbated by steroids in animals given non-steroidal anti-inflammatory drugs.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 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 3.3)

Lactation:

Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

3.8 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.

3.9 Administration routes and dosage

Oral use.
The veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

An overdose can induce drowsiness in horses.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QH02AB06

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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, 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 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.

5.3 Special precautions for storage

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

5.4 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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsgesellschaft mbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10810/017/001

8. DATE OF FIRST AUTHORISATION

15/11/2019

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

18/12/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).