

[Version 9.1,11/2024]

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

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, 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.

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)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

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

MM/YYYY

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 50 mg prednisolone

3. PACKAGE SIZE

50 tablets
100 tablets
200 tablets

4. TARGET SPECIES

Horses

Or instead of written text:



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 10 days.

Not authorised for use in mares producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life of divided tablets: 3 days.

9. SPECIAL STORAGE PRECAUTIONS

Return any divided tablet to the opened blister.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

CP-Pharma Handelsges. mbH

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equipred



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

50 mg prednisolone/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Equipred 50 mg tablets for horses

2. Composition

Each tablet contains:

Active substances:

50 mg prednisolone

White, convex tablet embossed with "50".

The tablet can be divided into halves and quarters.

3. Target species

Horses

To be included if the pictogram is printed on the outer package and/or blister:



4. Indications for use

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. Special warnings

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.

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 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.

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 section “Contraindications”)

Lactation:

Use only according to the benefit/risk assessment by the responsible veterinarian.

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.

Overdose:

An overdose can induce drowsiness in horses.

Major incompatibilities:

Not applicable.

7. Adverse events

Horses:

Very common (>1 animal / 10 animals treated):	Hypocortisolaemia ¹ (reduction in plasma cortisol) 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 (incoordination), Head tilt, Incoordination) Restlessness Recumbency, Anorexia (loss of appetite) Elevated serum alkaline phosphatase (ALP) ⁴ Gastrointestinal ulceration ⁵ , Colic Excessive sweating Urticaria (hives)

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 product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

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.

9. Advice on correct administration

10. Withdrawal periods

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. The expiry date refers to the last day of that month.

Return any divided tablets to the opened blister.

Any divided tablets remaining after 3 days should be discarded.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Blisters containing 10 tablets in cartons of 50, 100 or 200 tablets.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

<{MM/YYYY}>

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

CP-Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

Local representatives and contact details to report suspected adverse events:

17. Other information