SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cortico Veyxin
10 mg/ml suspension for injection for cattle, horses, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active substance:

Prednisolone acetate	10 mg
equivalent to prednisolone	8.95 mg

Excipients:

Benzyl alcohol (E1519)	9.45 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
The suspension after shaking is white and homogenous.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horse, dog and cat

4.2 Indications for use, specifying the target species

In horses, cattle, dogs and cats:
Supportive treatment of acute non-infectious arthritis, bursitis, tenosynovitis or allergic skin disease.

In cattle:
Supportive treatment of primary ketosis (acetonaemia).

4.3 Contraindications

Do not use in case of:

- Hypersensitivity to the active substance, to corticosteroids or to any of the excipients
- Gastrointestinal ulcers, poorly healing wounds, ulcers and fractures
- Viral infections during the viraemic stage or in cases of systemic mycotic infections
- In cows, during the last one-third of pregnancy
- General immunodeficiency
- Glaucoma, cataract and corneal ulcers
- Osteoporosis, hypocalcaemia

- Hyperadrenocorticism (e.g. Cushing's syndrome)
- Hypertension
- Pancreatitis
- Diabetes mellitus
- Renal insufficiency

Please see also section 4.5 *Special precautions for use in animals* and section 4.8 *Interaction with other medicinal products and other forms of interaction*.

4.4 Special warnings for each target species

Except in cases of acetonaemia, corticoid administration is to induce an improvement in clinical signs rather than a cure. The treatment should be combined with treatment of the underlying disease and/or environmental control.

4.5 Special precautions for use

Special precautions for use in animals

Conditions requiring special precautionary measures are:

- Diabetes mellitus (check blood values and increase insulin dose if necessary)
- Congestive heart failure (monitor carefully)
- Chronic renal failure (monitor carefully)
- Epilepsy (avoid long-term treatment)

Glucocorticoids should only be used with strict assessment of need in the case of:

- Growing animals and older or malnourished animals
- Lactating animals
- Pregnant animals because a possible teratogenic effect of prednisolone has not been sufficiently clarified
- Horses, since glucocorticoid induced laminitis may occur. Therefore, horses treated with such preparations should be monitored frequently during the treatment period.

Severe infections may occur during treatment with glucocorticoids. If infections occur, consult the treating veterinarian.
Regarding vaccination, a sufficient amount of time should be allowed in relation to glucocorticoid treatment. Active immunisation should not be performed during and for up to two weeks following glucocorticoid treatment. The development of adequate immunity may also be impaired in the case of preventive vaccination performed up to 8 weeks prior to the beginning of treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Prednisolone , propylene glycol and benzyl alcohol may cause hypersensitivity (allergic) reactions in sensitised people.
People with known hypersensitivity to prednisolone or any of the excipients should avoid contact with the product.
Prednisolone can cause harm to the unborn foetus; therefore, it is recommended that pregnant women avoid using this product.

Exposure to prednisolone may cause transient mood changes and gastrointestinal discomfort in some people.
Administration should be performed with caution in order to avoid accidental self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid contact with skin and eyes.
Accidental spillage onto skin or into the eyes should be rinsed off with water immediately.

4.6 Adverse reactions (frequency and seriousness)

Glucocorticoids, such as prednisolone acetate, are known to exert a wide range of side-effects.

- ACTH suppression, reversible adrenocortical atrophy due to inactivity
- Immunosuppression with increased risk of infection and negative effects on the course of infections
- Delayed wound and bone healing, osteoporosis, arthropathy, muscle wasting, and growth retardation including impairment of bone growth and damage to the bone matrix in young animals
- Diabetogenic effects resulting in reduced glucose tolerance, steroid-induced diabetes mellitus and deterioration of pre-existing diabetes mellitus
- Cushing syndrome
- Pancreatitis
- Lowering of the convulsive threshold, manifestation of latent epilepsy, euphoria-inducing effect, excitation states, rarely depression in cats, rarely depression or aggressiveness in dogs
- Skin atrophy
- Glaucoma, cataracts
- Polydipsia, polyphagia, polyuria
- Gastrointestinal ulcers
- Reversible hepatopathy
- Tendency to thrombosis
- Hypertension
- Sodium retention with development of oedema, hypokalaemia, hypocalcaemia
- Triggering of labour in cows in the last one-third of pregnancy, and afterwards, increased retention of placenta
- Transient decrease in milk production in cows
- Laminitis in the horse
- In the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.
- Decrease in thyroid hormone synthesis.
- Increase in parathyroid hormone synthesis.

4.7 Use during pregnancy, lactation or lay

Pregnancy:

There are risks associated with the use, especially systemically, of corticosteroids during pregnancy. The safety of the veterinary medicinal product in the target species has not been established. Systematic activity of corticosteroids in early pregnancy is known to have caused foetal abnormalities in laboratory animals after repeated treatment with doses considerably above the therapeutic level and in late pregnancy may cause early parturition or abortion and increased retention of placenta.

Hence the product should be used in pregnant animals only according to the benefit/risk assessment by the responsible veterinarian under strict establishment of the indication. Do not use in cows during the final one-third of pregnancy.

Lactation:
When used during lactation in cows, a transient reduction of milk production may occur. Use only in cases of strictly established need in lactating animals, since glucocorticoids cross into the milk and growth disturbances may occur in young animals.
Use during lactation only according to the benefit/risk assessment of the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

- Reduced tolerance to cardiac glycosides due to potassium deficiency
- Increased potassium loss with concomitant administration of thiazide and loop diuretics
- Elevated risk of gastrointestinal ulcers and gastrointestinal bleeding with concomitant administration of nonsteroidal anti-inflammatory drugs
- Decreased effect of insulin
- Phenytoin, barbiturates and ephedrine, may accelerate the metabolic clearance of corticosteroids resulting in decreased blood levels and reduced physiological effect.
- Concurrent use with anticholinesterase may lead to increased muscle weakness in patient with myasthenia gravis
- Increased intraocular pressure with concomitant administration of anticholinergics
- Reduced effect of anticoagulants
- Suppression of skin reactions in intracutaneous allergy tests

4.9 Amounts to be administered and administration route

For intramuscular use.
For single use.
Shake the suspension well before use.
The dosage needed may vary according to individual clinical circumstances such as the severity of the signs and the length of time for which they have been present.

Cattle, horse: 0.2 - 0.5 mg prednisolone acetate / kg body weight
corresponding to 2 - 5 ml of the product per 100 kg body weight

Dog, cat: 0.5 - 1 mg prednisolone acetate / kg body weight
corresponding to 0.05 - 0.1 ml of the product per kg body weight

The injection volume should not exceed 10 ml per injection site. If necessary, distribute the required injection volume over multiple sites.
The stopper should not be punctured more than 50 times.
Care should be taken not to overdose Channel Island breeds. Larger doses will be required if the signs have been present for some time or if relapsed animals are being treated.

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

In case of overdose, an increased rate of adverse effects is to be expected. There is no known antidote.

4.11 Withdrawal period(s)

Cattle: Meat and offal: 35 days
Milk: 24 hours

Horse: Meat and offal: 53 days
Not authorised for use in lactating mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids for systemic use, Glucocorticoids, Prednisolone
ATCvet code: QH02AB06

5.1 Pharmacodynamic properties

Prednisolone acetate is a synthetic glucocorticoid. In the animal's body, the acetate residue is cleaved from prednisolone acetate and the active component of the molecule – prednisolone – is released. In comparison with the endogenously synthesized cortisol, prednisolone has 4- to 5-times greater glucocorticoid activity, depending on the parameter examined (e. g. anti-inflammatory potency, glycogen storage in the liver), whereas its mineralocorticoid activity is slightly lower. Prednisolone intervenes in the hypothalamic-pituitary-adrenocortical axis by inhibition of ACTH synthesis (negative feedback), which causes inhibition of cortisol secretion in the adrenal gland and may cause after long term use adrenocortical insufficiency. Prednisolone exerts its pharmacologic action after passive uptake into the cells. Prednisolone primarily acts after binding to a cytoplasmic receptor and translocation into the nucleus, from which it causes a change in cell protein synthesis by influencing transcription and formation of specific mRNA. Basically prednisolone, like all glucocorticoids, affects carbohydrate (increased gluconeogenesis), protein (mobilization of amino acids by catabolic metabolic processes) and lipid metabolism (re-distribution of fat), and also exhibits anti-inflammatory, anti-allergic, membrane-stabilizing and immunosuppressive properties.

5.2 Pharmacokinetic particulars

After intramuscular administration of prednisolone acetate in animals, prednisolone is very slowly released by cleaving the acetate residue from prednisolone, mediated by endogenous esterases, then taken up into the systemic circulation and distributed throughout the body. As a result, prednisolone is gradually absorbed from the injection site over a long period and achieves a long-term effect. Approximately ¾ of prednisolone is bound to transcortin and albumin. Prednisolone readily crosses the blood-brain barrier, and crosses the placental barrier to differing degrees depending on the animal species. Small amounts also cross into the milk. Maximum plasma levels in the dog occur after approximately 2.9 hours, in cats after 4.4 hours and in the horse after 10.0 hours. Following intramuscular administration of the acetate, prednisolone is eliminated with a mean half-life of 28.5 hours in the dog and 48.5 hours in the cat.
Detectable prednisolone levels appear in the plasma of cattle within only about 15 minutes following intramuscular injection; maximum concentrations are reached 3-4 hours following administration. The mean elimination half-life in cattle is about 30.9 hours.

Prednisolone is transformed into various metabolites primarily in the liver, which, after reduction of a keto group, are conjugated to sulfuric acid or glucuronic acid and excreted via the bile and the kidney. Small amounts are also excreted unchanged.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Benzyl alcohol (E1519)
Polysorbate 80
Silica, colloidal anhydrous
Propylene glycol
Water for injection

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 immediate packaging: 14 days

6.4 Special precautions for storage
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging
Vial of colourless glass type II with bromobutyl rubber stoppers and aluminum caps.

1 vial (100 ml) in a cardboard box.
6 vials (100 ml) in a cardboard box.
12 vials (100 ml) in a cardboard box.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn
Germany

8. MARKETING AUTHORISATION NUMBER

Vm 27569/4007

9. DATE OF FIRST AUTHORISATION

25 September 2018

10. DATE OF REVISION OF THE TEXT

January 2023

Approved 11 January 2023