LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Cardboard box with 1, 6 or 12 vials

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
100 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Prednisolone acetate10 mg/ml

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

100 ml
6 x 100 ml
12 x 100 ml

5. TARGET SPECIES

Cattle, horse, dog and cat

6. INDICATION(S)

[Indication not to be included since required only for medicinal products not subject to medical prescription.]

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular injection.
Shake well before use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

Expiry date: month/year
Shelf life after first opening the immediate packaging: 14 days
Once opened, use by …..

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.

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

Disposal: read package leaflet.
[Not requested on the immediate label.]

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

Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 27569/4007

17. MANUFACTURER'S BATCH NUMBER

Batch number:

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
10 mg/ml suspension for injection for cattle, horses, dogs and cats
Prednisolone acetate

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn
Germany

Manufacturer responsible for the batch release:
Veyx-Pharma GmbH
Söhreweg 6
34639 Schwarzenborn
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

1 ml contains:

Active substance:

Prednisolone acetate	10 mg
equivalent to prednisolone	8.95 mg

Excipients:

Benzyl alcohol	9.45 mg

The suspension after shaking is white and homogenous.

4. INDICATION(S)

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).

5. CONTRAINDICATIONS

Do not use in cases 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 12 "Special warnings" for Special precaution for use and Interaction with other medicinal products and other forms of interaction.

6. ADVERSE REACTIONS

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.

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

Cattle, horse, dog and cat

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intramuscular injection.
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 i.m.
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.

For single use.

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.

9. ADVICE ON CORRECT ADMINISTRATION

None.

10. WITHDRAWAL PERIOD

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Shake the suspension well before administration.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 14 days
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package insert, the date on which any product remaining in the vial should be discarded should be worked out. This discard date should be written in the space provided on the label.
Keep the vial in the outer carton in order to protect from light.

12. SPECIAL WARNING(S)

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.

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.

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.

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

Overdose (symptoms, emergency procedures, antidotes):
In case of overdose, an increased rate of adverse effects is to be expected. There is no known antidote.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION>

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.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 11 January 2023