Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

CORTEXONAVET 2 mg/ml solution for injection for cattle, horses, pigs, dogs and cats

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Dexamethasone	2.0	mg
(as dexamethasone sodium phosphate)		

Excipients:

Benzyl alcohol (E1519)	15.6	mg

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless solution, free from visible particles.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, horses, pigs, dogs and cats.

4.2 Indications for use, specifying the target species

Horses, cattle, pigs, dogs and cats:
Treatment of inflammatory or allergic conditions.

Cattle:
Treatment of primary ketosis (acetonaemia). Induction of parturition

Horses:
Treatment of arthritis, bursitis or tenosynovitis.

4.3 Contraindications

Except in emergency situations, do not use in animals suffering from diabetes mellitus, renal insufficiency, cardiac insufficiency hyperadrenocorticism, or osteoporosis.
Do not use in viral infections during the viraemic stage or in cases of systemic mycotic infections.
Do not use in animals suffering from gastrointestinal or corneal ulcers, or demodicosis.
Do not administer by the intra-articular route where there is evidence of fractures, bacterial joint infections and aseptic bone necrosis.
Do not use in known cases of hypersensitivity to the active substance, to corticosteroids and to any of the excipients of the product.

Refer to section 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

Anti-inflammatory corticosteroids, such as dexamethasone, are known to exert a wide range of side effects. Whilst single high doses are generally well tolerated, they may induce severe side-effects in long term use and when esters possessing a long duration of action are administered. Dosage in medium to long term use should therefore generally be kept to the minimum necessary to control symptoms. Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon.

Use of corticosteroids in horses has been reported to induce laminitis. Therefore horses treated with such preparations should be monitored frequently during the treatment period.

During therapy effective doses suppress the hypothalamo-pituitreal-adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency extending to adrenocortical atrophy can arise and this may render the animal unable to deal adequately with stressful situations. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment (for further discussion see standard texts).

Because of the pharmacological properties of the active ingredient, special care should be taken when the product is used in animals with a weakened immune system.

Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of bacterial infection, antibacterial drug cover is usually required when steroids are used. In the presence of viral infections, steroids may worsen or hasten the progress of the disease.

Except in cases of acetonaemia and induction of parturition, corticosteroid administration is to induce an improvement in clinical signs rather than a cure.

The underlying disease should be further investigated. When treating groups of animals, use a draw- off needle to avoid excessive broaching of the stopper.

Following intra-articular administration, use of the joint should be minimized for one month and surgery on the joint should not be performed within eight weeks of use of this route of administration.

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

Care should be taken 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.

The veterinary medicinal product should not be administered by pregnant women.

People with known hypersensitivity to dexamethasone or to any of the excipients should avoid contact with the veterinary medicinal product.

Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash the area thoroughly with clean running water.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, hypersensitivity reactions may occur.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reactions during the course of one treatment)
- 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).

Steroids themselves, during treatment, may cause Cushingoid symptoms involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result.

Systemically administered corticosteroids may cause polyuria, polydipsia and polyphagia, particularly during the early stages of therapy. Some corticosteroids may cause sodium and water retention and hypokalaemia in long term use. Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis).

Gastro-intestinal ulceration has been reported in animals treated with corticosteroids and in animals with spinal cord trauma.

Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

Corticosteroid use may increase the risk of acute pancreatitis. Other possible adverse reactions associated with corticosteroid use include laminitis in horses and reduction in milk yield in cattle.

Corticosteroid use may induce changes in blood biochemical and haematological parameters. Transient hyperglycaemia can occur.

4.7 Use during pregnancy, lactation or lay

Pregnancy:
Apart from the use of the product to induce parturition in cattle, corticosteroids are not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion.
If the product is used for induction of parturition in cattle, then a high incidence of retained placentae may be experienced and possible subsequent metritis and/or subfertility. Such use of dexamethasone, particularly at early time points, may be associated with reduced viability of the calf.

Lactation:
Use of the product in lactating cows may cause a reduction in milk yield. See also section 4.6

4.8 Interaction with other medicinal products and other forms of interactions

Concurrent use with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.
Because corticosteroids can reduce the immune response to vaccination, dexamethasone should not be used in combination with vaccines or within two weeks after vaccination.
Administration of dexamethasone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides.
The risk of hypokalaemia may be increased if dexamethasone is administered together with potassium depleting diuretics.
Concurrent use with anticholinesterase may lead to increased muscle weakness in patients with myasthenia gravis.
Glucocorticoids antagonise the effects of insulin.
Concurrent use with phenobarbital, phenytoin and rifampicin can reduce the effects of dexamethasone.

4.9 Amounts to be administered and administration route

Routes of administration:
Horses: intravenous, intramuscular or intra-articular injection
Cattle, pigs, dogs and cats: intramuscular injection
Normal aseptic technique should be observed.
To measure small volumes of less than 1 ml, a suitably graduated syringe should be used to ensure accurate administration of the correct dose.

For the treatment of inflammatory or allergic conditions: The following average doses are advised. However the advised dose used should be determined by the severity of the signs and the length of time for which they have been present.

Species	*Dosage*
Horses, cattle, pigs	0.06 mg/kg body weight corresponding to 1.5 ml/50 kg
Dogs, cats	0.1 mg/kg body weight corresponding to 0.5 ml/10 kg

For the treatment of primary ketosis in cattle (acetonaemia) 0.02 to 0.04 mg/kg body weight corresponding to a dose of 5-10 ml per cow given by intramuscular injection is advocated dependent on the size of the cow and the duration of the signs. 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.

For the induction of parturition - to avoid foetal oversize and mammary oedema in cattle.
A single intramuscular injection of 0.04 mg/kg body weight corresponding to 10 ml per cow after day 260 of pregnancy. Parturition will normally occur within 48-72 hours.

For the treatment of arthritis, bursitis or tenosynovitis by intra-articular injection in the horse. Dose 1-5 ml
These quantities are not specific and are quoted purely as a guide. Injections into joint spaces or bursae should be preceded by the removal of an equivalent volume of synovial fluid. Strict asepsis is essential.

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

An overdose can induce drowsiness and lethargy in horses. Refer to section 4.6.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 8 days. Milk: 72 hours.
Pigs:
Meat and offal: 2 days.
Horses:
Meat and offal: 8 days.
Milk: Not authorised for use in horses producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids for systemic use, dexamethasone.
ATCvet code: QH02AB02

5.1 Pharmacodynamic properties

This preparation contains the sodium phosphate ester of dexamethasone, a fluoro-methyl derivative of prednisolone, which is a potent glucocorticoid with minimal mineralocorticoid activity. Dexamethasone has ten to twenty times the anti-inflammatory activity of prednisolone.
Corticosteroids suppress the immunologic response by inhibition of dilatation of capillaries, migration and function of leucocytes and phagocytosis. Glucocorticoids have an effect on metabolism by increasing gluconeogenesis.

5.2 Pharmacokinetic particulars

After extravascular (intramuscular, subcutaneous, intra-articular) administration, this soluble ester of dexamethasone is rapidly resorbed from the injection site followed by immediate hydrolysation into the parent compound, dexamethasone. Absorption of dexamethasone is rapid.
The time to reach maximum plasma concentrations (C_{max}) of dexamethasone in cattle, horses, pigs and dogs is within 20 min after intramuscular administration. Bioavailability following i.m. administration (compared to i.v. administration) is high in all species. Elimination half-life after intravenous administration in horses is 3.5 h. After intramuscular administration, apparent elimination half-life has been shown to range between 1 and 20 hours according to the species.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium chloride
Sodium citrate
Sodium hydroxide (for pH adjustment)
Citric acid monohydrate (for pH adjustment)
Water for injections.

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: 2 years.
Shelf life after first opening the immediate packaging: 28 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

Cardboard box with 1 colourless, type I glass vial of 50 or 100 ml, which is closed with a bromobutyl type I rubber stopper and sealed with an aluminium cap.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products 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

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Avda. Párraco Pablo Díez
49-57 León
24010
Spain

8 MARKETING AUTHORISATION NUMBER(S)

VPA10495/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 05 February 2016
Date of last renewal: 04 December 2020

10 DATE OF REVISION OF THE TEXT

December 2020