

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEXAMECINE 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 mg
As dexamethasone sodium phosphate	2.63 mg

Excipients:

Benzyl alcohol (E 1519)	15.6 mg
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For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Clear, colourless aqueous solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses, pigs, dogs and cats

4.2 Indications for use, specifying the target species

Horses

Treatment of inflammation and allergic reactions.

Treatment of arthritis, bursitis or tenosynovitis.

Cattle

Treatment of inflammation and allergic reactions.

Induction of parturition.

Treatment of primary ketosis (acetonemia).

Pigs

Treatment of inflammation and allergic reactions.

Dogs and cats

Treatment of inflammation and allergic reactions.

4.3 Contraindications

Except in emergency situations the product should not be used in animals suffering from diabetes, chronic nephritis, renal disease, congestive heart failure and osteoporosis.

For infectious diseases it is necessary that application of corticosteroids is associated with effective antibiotic or chemotherapeutic treatment.

Use of the product is contraindicated in immunodeficient animals, as well as in case of septic process, mycoses or parasitoses.

Do not use in animals affected by gastrointestinal or corneal ulcers, or demodecosis.

Do not use in case of aseptic bone necrosis, poor healing wounds or fractures.

Do not use in animals affected with Cushing's syndrome.

Do not use in animals suffering from cataract or glaucoma.

Do not use in pancreatitis, hypertonia, hypocalcaemia.

Do not use the veterinary medicinal product in the course of active vaccination.

Do not use in cases of known hypersensitivity to active substance or to any of the excipients.

4.4 Special warnings for each target species

None

4.5 Special precautions for use

Special precautions for use in animals

The induction of parturition with corticosteroids may be associated with reduced viability of calves, an increased incidence of retained placentae and possible subsequent metritis and/or subfertility in cattle.

Care should be taken when the product is used for the treatment of laminitis in horses, where there is the possibility that such treatment could worsen the condition.

The use of the product in horses for other conditions could induce laminitis and careful observation during the treatment period should be made.

During therapy effective doses suppress the hypothalamo-pituitary-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, e.g. dosing to coincide with the time of the endogenous cortisol peak (i.e. in the morning with regard to dogs and the evening regarding cats) and a gradual reduction of dosage.

Its use in younger or older individuals may be associated with an increased risk of side effects. Therefore, it is necessary to decrease the dose and clinical monitoring during treatment. During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

In the presence of bacterial infection, antibacterial drug cover is usually required when steroids are used.

In the presence of infections, steroids may worsen or hasten the progress of the disease.

Except in cases of ketosis 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.

Due to their immunosuppressive activity, corticosteroids can lead to a reduced response to vaccination. Therefore, it is recommended that product should not be used in combination with vaccines.

In suckling animals, the veterinary medicinal product should be used only according to the benefit-risk assessment by the responsible veterinarian.

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

Care should be taken to avoid accidental self-injection as dexamethasone can cause allergic reactions in some people.

People with known hypersensitivity to the dexamethasone should avoid contact with the veterinary medicinal product.

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

Dexamethasone may affect fertility or the unborn child. To avoid the risk from accidental self-injection, pregnant women should not handle this product.

This product is a skin and eye irritant. Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash/irrigate the area with clean running water.

Seek medical attention if irritation persists. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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.

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. Steroids may cause diabetogenic effects combined with reduced glucose tolerance, steroid induced or deterioration of existing diabetes mellitus.

Systematically 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).

Steroids may increase risk of thrombosis.

Administration of steroids leads to ACTH suppression and reversible inactivity atrophy of the suprarenal gland.

Lowering of convulsive threshold, possible manifestation of latent epilepsy, euphoric effects, excitation were observed after administration of corticosteroids.

Administration of corticosteroids may cause atrophy of the skin.

Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections and may delayed bone healing and arthropathy.

Gastro-intestinal ulceration has been reported in animals treated with corticosteroids and g.i.t. ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

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

Hypersensitivity reactions are possible, though rare.

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.

Corticosteroid use may increase the risk of acute pancreatitis.

Steroids may be related to behavioral changed in dogs and cats (occasional depression in cats and dogs, aggressiveness in dogs).

Other adverse reactions, such as hypertonia, edema, hypocalcemia, growth retardation with disruptive bone growth and damage of bone matrix and ophthalmic disorders (glaucoma, cataract) may be observed after administration of steroids.

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

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- 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).

4.7 Use during pregnancy, lactation or lay

Apart from the use of veterinary medicinal product to induce parturition in cattle, corticosteroids are not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused fetal 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. Use of the product corticosteroids in lactating cows may cause a temporary reduction in milk yield.

4.8 Interaction with other medicinal products and other forms of interaction

Because corticosteroids can reduce the immune response to vaccination, the product should not be used in combination with vaccines.

Dexamethasone should not be administered in conjunction with other anti-inflammatory substances since it increases the risk for gastric ulcers or intestinal bleeding.

Product administration may cause hypokalaemia thus increasing the risk of toxicity of cardiac glycosides.

The risk of hypokalemia can increase when dexamethasone is administered in conjunction with diuretics which influence on excretion of potassium.

Co-administration with cholinesterase inhibitors can lead to muscle weakness in patients suffering from myasthenia gravis.

Glucocorticoids antagonize insulin.

Co-administration of phenobarbital, phenytoin and rifampicin can suppress the effect of dexamethasone.

Increased intraocular pressure may occur when anticholinergic drugs such as atropine are administered simultaneously with dexamethasone.

Dexamethasone reduces effect of anticoagulants.

4.9 Amounts to be administered and administration route

Horses

Intramuscular or intraarticular administration.

Cattle, pigs, dogs and cats

Intramuscular administration.

For the treatment of inflammatory or allergic conditions the following doses administered as single intramuscular injection are advised:

Species	Dosage (i.m.)
Horses, cattle, pigs	0.06 mg of dexamethasone/kg bw (1.5 ml of product/50 kg bw)
Dog, cat	0.1 mg of dexamethasone/ kg bw (0.5 ml of product/10 kg bw)

For the treatment of primary ketosis in cattle a dose of 0.02-0.04 mg of dexamethasone/kg bw (5-10 ml of product per animal) given by single 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 (i.e. 0.04 mg/kg) 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 10 ml of product 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 of product *pro toto*

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.

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.

The cap should not be punctured more than 125 times. When treating groups of animals in one run, it is recommended to use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper.

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

High doses of corticosteroids may cause apathy and lethargy in the horses. High doses may cause thrombosis due to a higher tendency to blood clotting. Continuous overdosing may result in development of Cushing syndrome. See point 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

Not authorized for use in horses producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

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

5.1 Pharmacodynamic properties

Dexamethasone is a fluoro-methyl derivative of prednisolone, with anti-inflammatory, anti-allergic and immunosuppressive effect. Dexamethasone stimulates gluconeogenesis, which leads to an increase in blood sugar levels. Relative potency expressed by anti-inflammatory effect of dexamethasone is about 25 times higher than hydrocortisone, while its mineralocorticoid effect is minimal. Dexamethasone has shock preventing and parturition inducing effects.

5.2 Pharmacokinetic particulars

The product is a short acting dexamethasone preparation with a rapid onset of activity. It contains the disodium phosphate ester of dexamethasone. After extravascular (intramuscular, intra-articular) administration, the ester is rapidly resorbed from the injection site followed by immediate hydrolysis into the parent compound, dexamethasone. The time to reach maximum plasma concentrations (C_{max}) of dexamethasone in cattle, horse, pig and dog is within 20 min after administration. Bioavailability following i.m. administration approximately 100%. The half-lives of elimination after intravenous and intramuscular administration are 5-20 hours depending on the species.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium chloride
Sodium citrate
Citric acid monohydrate (for pH adjustment)
Sodium hydroxide (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: 36 months.
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

100 ml amber co-ex plastic (polypropylene) vials closed with bromobutyl rubber stoppers and aluminium caps.
The bottles are individually packaged in a cardboard box, the package leaflet is enclosed.

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

Vet-Agro Trading Sp. Z o.o.
Melgiewska str. 18
20-234 Lublin
Poland

8. MARKETING AUTHORISATION NUMBER

Vm 41715/4005

9. DATE OF FIRST AUTHORISATION

10 April 2018

10. DATE OF REVISION OF THE TEXT

July 2022

Approved 28 July 2022

A handwritten signature in black ink, appearing to read 'M. M. M.', located below the approval date.