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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E 1519)	15.6 mg
Sodium chloride	
Sodium citrate	
Citric acid monohydrate (for pH adjustment)	
Sodium hydroxide (for pH adjustment)	
Water for injections	

Clear, colourless aqueous solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, pigs, dogs and cats

3.2 Indications for use for each 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 (acetonaemia).

Pigs
Treatment of inflammation and allergic reactions.

Dogs and cats
Treatment of inflammation and allergic reactions.

3.3 Contraindications

Except in emergency situations the veterinary medicinal 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 veterinary medicinal 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 the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal 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 veterinary medicinal 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 the veterinary medicinal 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 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 veterinary medicinal product.
This veterinary medicinal product is a skin and eye irritant. Avoid contact with skin and eyes. In case of accidental eye or skin contact, wash/irrigate the area with clean running water. Seek medical attention if irritation persists. Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, horses, pigs, dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Euphoria Hypersensitivity reaction Immunosuppression, weakened resistance to or exacerbation of existing infections Polydipsia[1], polyphagia[1] Reduced growth rate[2], delayed wound healing Polyuria[1] Hepatomegaly Elevated liver enzymes, sodium and water retention[3], hypokalaemia[3] Cutaneous calcinosis[4], skin atrophy Acute pancreatitis, gastro-intestinal ulceration[5] Cushings disease[6] (e.g. redistribution of body fat, muscle weakness, muscle wasting and osteoporosis), diabetes mellitus[7]
Undetermined frequency (cannot be estimated from the available data):	Abnormal behaviour[8] (e.g. depression[8], aggression[9]), excitation Thrombosis Delayed bone healing Adrenocorticotropic hormone (ACTH) suppression, adrenal gland disorder (atrophy)[10] Glucose intolerance, hypocalcaemia Eye disorders (glaucoma, cataract) Oedema Arthropathy Convulsion[11], epileptic seizure[12], hypertonia Retained placenta[13], metritis[13,14], subfertility[13,14]

[1] after systemic administration and particularly during the early stages of therapy
[2] with disruptive bone growth and damage of bone matrix
[3] in long term use
[4] caused by systemic corticosteroids
[5] May be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
[6] Cushingoid symptoms, involving significant alteration of fat, carbohydrate, protein and mineral metabolism.
[7] steroid induced or deterioration of existing
[8] in dogs and cats
[9] in dogs
[10] reversible, caused by inactivity
[11] due to lowering of convulsive threshold
[12] possible manifestation of latent epilepsy
[13] in cattle, when use for induction of parturition
[14] subsequent to retained placenta

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.

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

Pregnancy and lactation:

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 veterinary medicinal 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.

3.8 Interaction with other medicinal products and other forms of interaction

Because corticosteroids can reduce the immune response to vaccination, the veterinary medicinal 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.
Veterinary medicinal product administration may cause hypokalaemia thus increasing the risk of toxicity of cardiac glycosides.
The risk of hypokalaemia 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.

3.9 Administration routes and dosage

Horses
Intramuscular or intraarticular use.

Cattle, pigs, dogs and cats
Intramuscular use.

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 veterinary medicinal product/50 kg bw)
Dogs, cats	0.1 mg of dexamethasone/kg bw (0.5 ml of veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal 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.

To ensure a correct dosage, body weight should be determined as accurately as possible.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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 section 3.6.

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

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH02AB02

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

The veterinary medicinal 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 hydrolysation 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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

5.5 Special precautions for the disposal of unused veterinary medicinal product 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

Vet-Agro Trading Sp. Z o.o.

7. MARKETING AUTHORISATION NUMBER

Vm 41715/4005

8. DATE OF FIRST AUTHORISATION

10 April 2018

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

November 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Approved 06 February 2025

Gavin Hall