SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexadreson 2 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Dexamethasone (as sodium phosphate) 2 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	15.6 mg
Sodium chloride	
Sodium citrate dihydrate	
Sodium hydroxide (for pH adjustment)	
Citric acid (for pH adjustment)	
Water for injections	

Clear, colourless solution for parenteral injection.
pH 7.0 - 7.8.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, pigs, dogs and cats.

3.2 Indications for use for each target species

The product may be used whenever a parenteral corticosteroid preparation giving a medium duration of activity is indicated. It can be used as an anti-inflammatory and anti-allergic agent in horses, cattle, pigs, dogs and cats and for the treatment of primary ketosis in cattle. The product can also be used to induce parturition in cattle. The product is suitable for intravenous use in the horse and is thus of particular benefit in cases needing emergency treatment.

3.3 Contraindications

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

3.4 Special warnings

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.

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 clinical signs. During a course of treatment the situation should be reviewed frequently by close veterinary supervision.
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. During therapy effective doses suppress the hypothalamo-pituitreal-adrenal axis. Following cessation of treatment, signs 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 for cats) and a gradual reduction of dosage (for further discussion see standard texts).

Corticosteroids may delay wound healing and the immunosuppressive effect can weaken the immune system or worsen pre-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.

Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal tract ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

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

The veterinary medicinal product can cause allergic reactions. People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product.

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.
To avoid the risk of self-injection, pregnant women should not handle the veterinary medicinal product.

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.

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):	Polyuria[1] Polydipsia[1] Polyphagia[1] Hepatomegaly Elevated liver enzymes Other blood disorder (retention of water, sodium and hypokalemia)[2] Cutaneous calcinosis Delayed healing Hypersensitivity

[1] Particularly during the early stages of therapy.
[2] During long term use.

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 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.
Use of the product in lactating cows may cause a 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 product should not be used in combination with vaccines.

3.9 Administration routes and dosage

Cattle, pigs, dogs and cats: Intramuscular use.
Horses: Intravenous, intramuscular or intra-articular use.

Normal aseptic technique should be observed.

For the treatment of inflammatory or allergic conditions: The following average doses are advised. However, the actual 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	1.5 ml/50 kg
Dogs, cats	0.5 ml/10 kg

For the treatment of primary ketosis in cattle: A dose of 5-10 ml 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 10 ml 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.

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

To measure small volumes of less than 1 ml a suitably graduated syringe should be used to ensure accurate administration of the correct dose.

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

Refer to 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

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.

Following intramuscular injection this soluble ester of dexamethasone is rapidly absorbed and hydrolysed to the parent alcohol giving a prompt response which is maintained for approximately 48 hours.

4.3 Pharmacokinetics

This 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, subcutaneous, intraarticular) administration, the ester 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 (Cmax) of dexamethasone in cattle, horses, pigs and dogs is within 20 minutes after intramuscular administration. Bioavailability following intramuscular. administration (compared to intravenous. administration) is high in all species. Elimination half-life after intravenous administration in horses is 3.5 hours. After intramuscular administration, apparent elimination half-life has been shown to range between 1 and 20 hours according to the species.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix the product with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25 °C.
Protect from light.

5.4 Nature and composition of immediate packaging

50 ml clear, Type I, glass vials with a halogenobutyl rubber stopper, closed with a colour coded aluminium cap.

Pack size:
Cardboard box containing a 50 ml vial.

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.

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

Intervet International B.V.

7. MARKETING AUTHORISATION NUMBER

Vm 06376/4085

8. DATE OF FIRST AUTHORISATION

04 November 1994

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

July 2025

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.

Gavin Hall
Approved: 13 August 2025