1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexadreson 2 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 ml contains:

Active substance:

Dexamethasone (as sodium phosphate) 2.0 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.

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, pigs, dogs and cats.

3.2 Indications for use for each target species

The veterinary medicinal 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 veterinary medicinal product can also be used to induce parturition in cattle. It is suitable for intravenous use in horses and is thus of particular benefit in cases needing emergency treatment.

3.3 Contraindications

Except in emergency situations, do not use in animals suffering from diabetes mellitus, chronic nephritis, renal disease, congestive heart failure, osteoporosis and in viral infections during the viraemic stage.

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

3.4 Special warnings

Use of the veterinary medicinal product in horses could predispose to laminitis and therefore, careful observation during treatment is necessary.

3.5 Special precautions for use

Special precautions for safe use in the target species:
During a course of treatment, the clinical status should be monitored by close veterinary supervision.
Anti-inflammatory corticosteroids, such as the veterinary medicinal product, 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.

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.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses, cattle, pigs, dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Polyuria[1] Polydipsia[1] Polyphagia[1] Ulceration[2] Hepatomegaly Elevated liver enzymes Electrolyte disorder (hypokalaemia, sodium retention, water retention)[3] Cutaneous calcinosis Hypersensitivity reaction Cushings disease (Iatrogenic hyperadrenocorticism)[4]

[1] Particularly during the early stages of therapy.
[2] Gastro-intestinal ulceration in animals treated with corticosteroids and with spinal cord trauma.
[3] During long term use.
[4] Involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result.

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 the national competent authority via the national reporting system. See package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Apart from the use of the 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 foetal 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. Such use, particularly at early time points, may be associated with reduced viability of the calf.

Lactation:
Use of the veterinary medicinal product in lactating cows may cause a reduction in milk yield.

3.8 Interaction with other medicinal products and other forms of interaction

Corticosteroids can depress the immune response. The veterinary medicinal product should therefore not be used in combination with vaccines.
Gastro-intestinal ulceration may be exacerbated by corticosteroids in patients given non-steroidal anti-inflammatory drugs.

3.9 Administration routes and dosage

Routes of administration:
Horses: Intravenous, intramuscular or intraarticular use.
Cattle, pigs, dogs and cats: Intramuscular use.

Use normal aseptic techniques.
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:	1.5 ml/50 kg
Dogs, cats:	0.5 ml/10 kg

For the treatment of primary ketosis in cattle (*acetonaemia*):
A dose of 5-10 ml 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. In most early cases a single dose will effect a cure.

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 use in horses.
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.

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

No effects other than those described in section 3.5 and 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.

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: 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

Clear glass (Type I Ph. Eur.) vials of 50 ml closed with a halogenated butyl rubber stopper and sealed with an aluminium cap.

5.5 Special precautions for the disposal of unused veterinary medicinal products 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

Intervet Ireland Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/027/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

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

12/08/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).