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 2.0 mg
(as dexamethasone sodium phosphate)

Excipient
Benzyl alcohol (E1519) 15.6 mg

For the full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses, cattle, pigs, dogs and cats.

4.2 Indications for use, specifying the target species

Dexadreson 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. Dexadreson is suitable for intravenous use in the horse and is thus of particular benefit in cases needing emergency treatment.

4.3 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.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precautions for use in animals
During a course of treatment the clinical status should be monitored by close veterinary supervision.
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.

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).

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 medicinal product to animals
Not applicable.

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 displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, 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.

4.7 Use during pregnancy, lactation or lay

Apart from the use of Dexadreson 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.
Use of the product in lactating cows may cause a reduction in milk yield.

4.8 Interaction with other medicinal products and other forms of interaction

Corticosteroids can depress the immune response. Dexadreson 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.

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.

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
Dog, cat	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 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

No effects other than those described in section 4.5 and 4.6.

4.11 Withdrawal Period(s)

Meat and offal: Cattle: 8 days.
Pigs: 2 days.
Horses: 8 days.
Milk: Cattle: 72 hours.
Horses: 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 product 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
Sodium chloride
Sodium citrate
Sodium hydroxide
Citric acid
Water for injections

6.2 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: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

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

6.5 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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/027/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989

Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

July 2016