SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexadreson 2 mg/ml solution for injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	per ml:
Dexamethasone	2 mg
as dexamethasone sodium phosphate	2.63 mg

Excipients:

Benzyl alcohol	15.6 mg

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear aqueous solution.

4 CLINICAL PARTICULARS

4.1 Target species

Cattle, horses, pigs, dogs and cats

4.2 Indications for use, specifying the 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.

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, osteoporosis and in viral infections during the viraemic stage.

4.4 Special warning for each target species

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.

4.5 Special precautions for use

(i) Special precautions for use in animals

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 a course of treatment the situation should be reviewed frequently by close veterinary supervision.

(ii) Special precautions to be taken by the person administering the medicinal product to the animals

The veterinary medicinal product can cause allergic reactions. Persons with known hypersensitivity to the active substance or 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 insert 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.

4.6 Adverse reactions (frequency and seriousness)

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, 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 re cats) and a gradual reduction of dosage (for further discussion see standard texts).

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).*

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.

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.

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.

Use of the product in lactating cows may cause a reduction in milk yield.

In very rare cases, hypersensitivity reactions might occur.

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

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

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

May be administered by intravenous or intramuscular injection in horses, and by intramuscular injection in cattle, pigs, dogs and cats. The product may also be given by intra-articular injection in horses. 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
Dog, cat	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 measure small volumes of less than 1 ml a suitably graduated syringe should be used to ensure accurate administration of the correct dose.

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

See 4.6 above.

4.11 Withdrawal period(s)

Cattle:
Meat and offal: 8 days
Milk: 72 hours

Pigs:
Meat: 2 days

Horses:
Meat and offal: 8 days
Not authorised for use in horses producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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.
ATC VetCode: QH02AB02

5.2 Pharmacokinetic particulars

Dexadreson is a short acting dexamethasone preparation with a rapid onset of activity. It contains the disodium phosphate ester of dexamethasone. After extravascular (intramuscular, subcutaneous, intra-articular) 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, horse, pig and dog is within 20 min after intramuscular administration. Bioavailability following i.m. administration (compared to i.v. administration) is high in all species. Elimination half-life after intravenous administration in horses is 3.5 h. After intramuscular administration, apparent elimination half-life has been shown to range between 1 and 20 hours according to the species.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

benzyl alcohol
sodium chloride
sodium citrate dihydrate
citric acid solution – (for pH adjustment)
sodium hydroxide solution – (for pH adjustment)
water for injections

6.2 Incompatibilities

Do not mix the product with other 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. Following the withdrawal of the first dose, use the product within 28 days. Discard unused material.

6.5 Nature and composition of immediate packaging

A 50 ml clear, Glass Type I (Ph.Eur) vials with halogenobutyl rubber stopper, closed with a colour coded aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4323

9. DATE OF FIRST AUTHORISATION

04 November 1994

10. DATE OF REVISION OF THE TEXT

March 2022

Approved 15 March 2022