

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafort Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Dexamethasone sodium phosphate	1.32 mg
Dexamethasone phenylpropionate	2.67 mg

Excipients:

Benzyl alcohol (E 1519)	10.4 mg
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For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Suspension for injection.
White to off-white suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, cattle, dogs and cats.

4.2 Indications for use, specifying the target species

The product is indicated for use as an anti-inflammatory and anti-allergic agent in horses, cattle, dogs and cats, and for the treatment of primary ketosis in cattle. The product can also be used to induce parturition in cattle.

4.3 Contra-indications

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

See 4.6 below.

4.5 Special precautions for use

- (i) Special precautions for use in animals

Shake vial well before use. See 4.3 above and 4.6 below.

- (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)

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.

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-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, eg dosing to coincide with the time of the endogenous cortisol peak (ie 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*).

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.

In very rare cases, hypersensitivity reactions might occur.

Care should be taken when the product is used for the treatment of laminitis in horses, where there is a possibility that such treatment could worsen the condition. The use of the product in horses for other conditions could induce laminitis and careful observations during the treatment period should be made.

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

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.

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

Systemic corticosteroid therapy is generally contra-indicated in patients with renal disease and diabetes mellitus. 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.

4.7 Use during pregnancy or lactation

Apart from the use of the 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.

4.8 Interaction with other medicinal products and other forms of interaction

See 4.6 above.

4.9 Amounts to be administered and administration route

Before use shake vial upright thoroughly for 30 seconds.

Dexafort should be administered by intramuscular injection using normal aseptic techniques by use of a min. 21 G cannula.

Dexafort should be administered by intramuscular injection using 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	1 ml/50 kg
Dog, cat	0.5 ml/10 kg

the treatment of primary ketosis in cattle (acetoaemia)

A dose of 5-10 ml dependent on the size of the cow. Since blood sugar levels rise rapidly following injection of the product, through the action of dexamethasone sodium phosphate and raised levels are maintained for several days, the product is particularly useful in cases that present late and there is seldom a need to repeat the dose.

In the case of cows in poor bodily condition, to avoid prolonged stimulation of gluconeogenesis at the expense of body fat reserves, use a product containing only the quick-acting ester.

For the induction of parturition

The product may be used to induce parturition in cattle in the last trimester and before day 260 of pregnancy. Where this is required e.g. in the cases of trauma to the cow or possibly because the date of calving is not known a single dose of 10 ml followed 6-12 days later by an injection of a short acting corticosteroid such as dexamethasone sodium phosphate alone is recommended. In the majority of cases parturition will be induced within 3 days of the second injection.

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

See 4.6 above.

4.11 Withdrawal periods

Cattle: Meat – 63 days
Milk – 144 hours

Not to be used in horses intended for human consumption.

Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: glucocorticoid
ATC code: QH02AB02

Dexamethasone is a highly potent corticosteroid. It has minimal mineralocorticosteroid activity and potent glucocorticosteroid activity. Dexamethasone has gluconeogenic, anti-inflammatory, anti-allergenic activity and it induces parturition. Dexafort is a dexamethasone preparation with a rapid onset of activity and a relatively long duration of action. It contains the disodium phosphate ester and phenylpropionate ester of dexamethasone.

5.2 Pharmacokinetic particulars

After intramuscular administration, the two dexamethasone esters are resorbed from the injection site followed by immediate hydrolysis into the parent compound, dexamethasone. Dexamethasone sodium phosphate is resorbed rapidly from the injection site, thus ensuring a rapid onset of activity.

Dexamethasone phenylpropionate is resorbed more slowly from the injection site, thus ensuring a prolonged duration of activity.

The time to reach maximum plasma levels of dexamethasone after intramuscular injection in cattle, horse, and dog is within 60 min after injection. Elimination half-lives after intramuscular administration are between 30 and 96 hours depending on the species. This relatively long half-life is caused by the relatively slow resorption of dexamethasone phenylpropionate from the injection site and is a combination of absorption and elimination half life. Bioavailability after intramuscular administration is approximately 100%.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol (E1519)
Sodium Chloride
Sodium Citrate Dihydrate (E331)
Methylcellulose
Tragacanth (E413)
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: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Keep the container in the outer carton in order to protect from light.
Store in upright position.
Following withdrawal of the first dose, use within 28 days.

Discard unused material.

6.5 Nature and composition of immediate packaging

Clear glass (Type I Ph.Eur) vials of 50 ml closed with a bromobutyl rubber stopper and aluminium overseal with or without a blue flip-off 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 01708/4324

9. DATE OF FIRST AUTHORISATION

4 November 1994

10. DATE OF REVISION OF TEXT

March 2022

Approved 23 March 2022



