1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafort injectable suspension for cattle, horse, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

Active substance:

Dexamethasone phenyl propionate:	2.67 mg (equivalent to 2 mg dexamethasone)
Dexamethasone sodium phosphate:	1.32 mg (equivalent to 1 mg dexamethasone)

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Aqueous suspension for injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horse, dog and cat

4.2 Indications for use, specifying the target species

Treatment of inflammatory and allergic conditions in horses, cattle, dogs and cats
Treatment of ketosis in cattle
Induction of parturition in cattle

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, and osteoporosis and in viral infections during the viraemic stage.
Do not use to treat infectious diseases unless suitable anti-infective therapy is given at the same time.
Do not use in animals suffering from gastrointestinal or corneal ulcers, or demodicosis.
Do not use in animals suffering from Cushing disease.

4.4 Special warnings for target species

The induction of parturition with corticosteroids in cattle may be associated with reduced viability of the offspring and an increased incidence of retained placenta.
Use of the product in lactating cows may cause a reduction in milk yield.
In case of laminitis in horses, the product should only be used very early in the disease process.
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 a gradual reduction of dosage.
Use on younger or older individuals, can cause increased risk of side effects. A reduced dose and clinical observation during treatment is therefore necessary.
During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

4.5 Special precautions for use

Special precautions for use in animals
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. Except for the treatment of ketosis and induction of parturition corticosteroids ameliorate, rather than cure, the conditions for which they are used. Therefore, it is advised to diagnose the fundamental cause.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Care should be taken to avoid accidental self-injection. If accidental self–injection occurs, seek medical attention and show the label to the physician.
Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash the area with clean water. Seek medical attention if irritation persists. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)
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.

Steroids themselves, during treatment, may cause Cushinoid 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).

Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections.

Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastro-intestinal-tract-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.

Hypersensitivity reactions are possible, even if rare.

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).

4.7 Use during pregnancy, lactation or lay
Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion. Therefore, administration during pregnancy is only recommended based on a positive risk-benefit analysis by the responsible veterinarian.
If the product is used for induction of parturition in cattle a high incidence of retained placentae may be experienced and possible subsequent metritis and/or subfertility.

4.8 Interaction with other medicinal products and other forms of interaction

Because corticosteroids can reduce the immune response to vaccination, dexamethasone should not be used in combination with vaccines.
Dexamethasone should not be given together with other anti-inflammatory drugs.
Administration of dexamethasone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypokalaemia may be increased if dexamethasone is administered together with potassium depleting diuretics.
Concurrent use with anticholinesterase may lead to increased muscle weakness in patients with myasthenia gravis.
Glucocorticoids antagonise the effects of insulin.
Concurrent use with phenobarbital, phenytoin and rifampicin can reduce the effects of dexamethasone.

4.9 Amounts to be administered and administration route

Shake well before use.
Horse, cattle: 0.02 ml/kg (0.06 mg/kg) by intramuscular route
Dog, cat: 0.05 ml/kg (0.15 mg/kg) by intramuscular or subcutaneous routes
Treatment may be repeated after 7 days.

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

High doses of corticosteroids may cause drowsiness and lethargy in horses.
See also point 4.6.

4.11 Withdrawal periods

Cattle:	Meat:	53 days
	Milk:	11 milkings
Horse:	Meat:	47 days

These withdrawal periods apply to the intramuscular route.
Do not use in horses producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: glucocorticoid
ATC code: QH02AB02

5.1 Pharmacodynamic properties

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 activity. 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 hydrolysation 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 resorption and elimination half-life. Bioavailability after intramuscular administration is approximately 100%.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Water for injection
Benzyl alcohol
Sodium citrate
Sodium chloride
Tragacanth
Methylcellulose
Sodium hydroxide
Hydrochloric acid

6.2 Incompatibilities
None known

6.3 Shelf life
Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first use: 28 days.

6.4. Special precautions for storage
Store in an upright position

6.5 Nature and composition of immediate packaging
Glass type I, vials are closed with a halogenated butylrubber stopper and sealed with an aluminium cap. Vials contain 50 ml

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products
No special precautions required. Discard by appropriate channels.