INJECTABLE AQUEOUS SOLUTION OF DEXAMETHASONE

2 mg Dexamethasone (as sodium phosphate) per mL.

50 mL

Read entire carton and leaflet before use

PRESENTATION

A clear aqueous solution for injection. Each mL contains 2 mg dexamethasone (as 2.63 mg dexamethasone sodium phosphate).

INDICATIONS

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.

Dexadreson may be used whenever a parental 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 as supportive therapy in cases of shock in horses.

DOSAGE AND ADMINISTRATION

Dexadreson may be administered by intravenous, intramuscular or subcutaneous injection in horses, sheep, goats, cattle, pigs, dogs and cats. The product may also be given by intra-articular injection in horses.

Normal aseptic techniques should be observed. 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 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, sheep and goats	1.5mL/50kg
Dogs, cats	0.5mL/10kg
Doses may be repeated once at 24-48 hour	r intervals if required.

All parenteral routes may be used in all species. The intravenous route is particularly useful when a rapid response is required. In shock, administer slow i.v. 4-11 mg/kg. During prolonged therapy, anabolic steroids should be given to counteract any possible catabolic breakdown of tissues.

For the treatment of primary ketosis in cattle (acetonaemia):

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. In most early cases a single dose will effect a cure but the dose may be repeated at 48 hour intervals if necessary.

As supportive treatment in cases of shock in horses: Intravenous doses of 4-6 mg/kg can be administered. For the treatment of arthritis, bursitis or tenosynovitis in horses:

Dose 1-5mL by intra-articular injection in the horse.

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.

WITHDRAWAL

Pituitary/adrenal suppression by Dexadreson is particularly effective and carefully controlled withdrawal is necessary. Daily dosage rates should first be reduced, followed by a reduction to dosing on alternate days until treatment is stopped. A.C.T.H. stimulation is advisable if courses have been prolonged.

CONTRAINDICATIONS, WARNINGS ETC

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.

- Anti-inflammatory corticosteroids, such as dexamethasone, are known to exert a wide range of sideeffects. 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.
- 2. Steroids themselves, during treatment, may cause Cushingnoid symptoms involving significant alternation of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, muscle weakness and wastage and osteoporosis may result.
- 3. During therapy effective doses suppress the hypothalamo-pituitary -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 treatments, 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 information see standard texts).
- 4. 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).
- 5. 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 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.
- 7. Gastrointestinal 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.
- 8. Care should be taken when the product is used for the treatment of laminitis in horses, 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.
- 9. Use of the product in lactating cows may cause a reduction in milk yield.
- 10. During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

WITHHOLDING TIMES

It is an offence for users of this product to cause residues exceeding the relevant MRL in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards.

Meat: Animals producing meat or offal for human consumption must not be sold for slaughter either during treatment or within **1 day** (cattle), **63 days** (horses and pigs) or **91 days** (sheep and goats) of the last treatment.

Milk: Milk intended for sale for human consumption must be discarded during treatment and for not less than **2 milkings** or approximately **24 hours** (cows) or **35 days** (sheep and goats) following the last treatment.

Do not use in bobby calves.

SAFETY DIRECTIONS

Warning - suspected of damaging fertility or the unborn child. Wash hands immediately after use.

FIRST AID

If exposed or concerned get medical advice. For advice contact a doctor or the National Poisons Centre 0800 POISON (0800 764 766).

In case of accidental self- injection: Obtain medical attention - show this leaflet and/or Safety Data Sheet.

DISPOSAL

Dispose of unused contents in a suitable landfill. Dispose of empty container by burying in a suitable landfill, or recycling. *See Safety Data Sheet for further information*. www.msd-animal-health.co.nz

STORAGE

Store at room temperature, below 25°C. Do not refrigerate or freeze. Once opened Dexadreson can be stored for up to 4 weeks at room temperature.

ACVM Registration No. A1421 See www.foodsafety.govt.nz for registration conditions. Dexadreson is a registered trademark. © 2013

Registered to: Schering-Plough Animal Health Ltd Phone: 0800 800 543 www.msd-animal-health.co.nz

