LIVISTO

DEXAFAST

2 mg/ml

SPEED AND POWER

Dexamethasone solution for injection for horses, cattle, pigs, dogs and cats

Along with you

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2 mg/ml

Dexamethasone solution for injection for horses, cattle, pigs, dogs and cats

SPEED AND POWER

FAST ACTION
With rapid resorption after injection and fast absorption.[1]

POTENT ANTI-INFLAMMATORY
It is a potent glucocorticoid with 10 to 25 times more anti-inflammatory activity than prednisolone and cortisol.[1-3]

DEXAFAST 2 mg/ml solution for injection for horses, cattle, pigs, dogs and cats: Composition: Each ml contains: Dexamethasone 2.0 mg.
Pharmaceutical Form: Solution for injection.
Clear, colourless solution.
Target species: Horses, cattle, pigs, dogs and cats.
Indications for use: Horses, cattle, pigs, dogs and cats: Treatment of inflammatory or allergic conditions.
Cattle: Induction of parturition. Treatment of primary ketosis (acetonaemia).
Horses: Treatment of arthritis, bursitis or tenosynovitis.
Contraindications: Except in emergency situations, do not use in animals suffering from diabetes mellitus, renal insufficiency, cardiac insufficiency, hyperadrenocorticism or osteoporosis. Do not use in viral infections during the viraemic stage or in cases of systemic mycotic infections. Do not use in animals suffering from gastrointestinal or corneal ulcers, or demodicosis. Do not administer intra-articularly where there is evidence of fractures, bacterial joint infections and aseptic bone necrosis. Do not use in known cases of hypersensitivity to the active substance, to corticosteroids and to any other ingredient of the product.
Special precautions for use: Special precautions for use in animals: Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon. Use of corticosteroids in horses has been reported to induce laminitis. Therefore, horses treated with such preparations should be monitored frequently during the treatment period. Because of the pharmacological properties of the active ingredient, special care should be taken when the product is used in animals with a weakened immune system. Except in cases of acetonemia and induction of parturition, the purpose of corticosteroid administration is to produce an improvement in clinical signs rather than a cure. The underlying disease should be further investigated. Following intra-articular administration, use of the joint should be minimized for one month and surgery on the joint should not be performed within eight weeks of use of this route of administration.
Special precautions to be taken by the person administering the veterinary medicinal product to animals: Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet to the doctor. Pregnant women should not handle this veterinary medicinal product. Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash the area thoroughly with clean running water. People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the product. Wash hands after use.

Adverse reactions: 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. During medium to long term use the dose should therefore generally be kept to the minimum necessary to control symptoms. Steroids themselves, during treatment, may cause iatrogenic hyperadrenocorticism (Cushing's disease) 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 (for further discussion see standard texts). 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 upon 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. Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal 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. Corticosteroid use may induce changes in blood biochemical and haematological parameters. Transient hyperglycaemia can occur. 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. Corticosteroid use may increase the risk of acute pancreatitis. Other possible adverse reactions associated with corticosteroid use include laminitis and reduction in milk yield. In very rare cases, hypersensitivity reactions may occur.
Use during pregnancy, lactation or lay: 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. Use of the product in lactating cows may cause a reduction in milk yield.
Interaction with other medicinal products and other forms of interaction: Concurrent use with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration. Because corticosteroids can reduce the immune response to vaccination, dexamethasone should not be used in combination with vaccines or within two weeks after vaccination. 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.
Amounts to be administered and administration route: For the treatment of inflammatory or allergic conditions: Cattle and pigs: IM injection: 0.06 mg dexamethasone /kg body weight corresponding to 1.5 ml/50 kg
Horses: IV, IM or intra-articular injection: 0.06 mg dexamethasone /kg b.w. corresponding to 1.5 ml/50 kg
Dogs and cats: IM injection: 0.1 mg dexamethasone /kg b.w. corresponding to 0.5 ml/10 kg
For the treatment of primary ketosis in cattle (acetonaemia): 0.02 to 0.04 mg dexamethasone /kg b.w. corresponding to a dose of 5-10 ml of the product per 500 kg b.w. given by IM 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 (up to 0.06 mg dexamethasone/kg) 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 IM injection of 0.04 mg dexamethasone /kg b.w. corresponding to 10 ml of the product per 500 kg b.w. 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 horses: Dose 1 – 5 ml of the product.
Overdose: An overdose can induce drowsiness and lethargy in horses.
Withdrawal periods:
Cattle: Meat and offal: 8 days. Milk: 72 hours.
Pigs: Meat and offal: 2 days
Horses: Meat and offal: 8 days. Milk: Not authorised for use in horses producing milk for human consumption
Shelf life: 30 months. **Shelf life after first opening the immediate packaging:** 28 days.
Special precautions for storage: Keep the vial in the outer carton in order to protect from light.
Nature and composition of immediate packaging: Clear glass vials of 50 ml and 100 ml.
Marketing Authorisation Holder:
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References

1. DEXAFAST. Summary of product characteristics.

2. Papich, M. G. Dexamethasone Sodium Phosphate. *Saunders Handb. Vet. Drugs* 219–221 (2016).

3. Brunton, L. et al. in *Goodman and Gilman's The Pharmacological Basis of Therapeutics* 1216 (Goodman&Gilman's, 2011).

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Date of preparation: Feb 2019. FOR090