Dexium-SP™

(dexamethasone sodium phosphate injection)

INJECTION USP FOR HORSES

4 mg/mL Equivalent to dexamethasone 3 mg/mL

FOR INTRAVENOUS USE IN HORSES ONLY
NOT FOR USE IN HUMANS
KEEP OUT OF REACH OF CHILDREN
WARNING: DO NOT USE IN HORSES INTENDED FOR HUMAN CONSUMPTION

CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Dexamethasone sodium phosphate (a synthetic adrenocortical steroid) is a white or slightly yellow crystalline powder. It is freely soluble in water and is exceedingly hygroscopic.

Each mL of Dexium-SP (dexamethasone sodium phosphate injection) contains Dexamethasone Sodium Phosphate 4 mg (equivalent to dexamethasone 3 mg), Sodium Citrate 10 mg, Sodium Bisulfite 2 mg, Benzyl Alcohol 1.5% as preservative, in Water for Injection q.s. Sodium Hydroxide and/or Hydrochloric Acid to adjust pH to between 7.0 and 8.5.

CLINICAL PHARMACOLOGY

Dexamethasone is a synthetic corticosteroid and possesses glucocorticoid activity. Dexamethasone sodium phosphate is a salt of dexamethasone that is particularly suitable for intravenous administration because it is highly water soluble, permitting administration of relatively large doses in a small volume of diluent.

Dexamethasone, as a steroid, is equivalent in potency to some established steroids while being considerably more potent than others. In the case of the dog, dexamethasone is found to be about equivalent in dosage to prednisone but about 30 to 40 times more potent than prednisolone.

INDICATIONS AND USAGE

Dexium-SP (dexamethasone sodium phosphate injection) is indicated as a rapid adrenal glucocorticoid and/or anti-inflammatory agent in horses.

CONTRAINDICATIONS

Do not use in viral infections. Except when used for emergency therapy, dexamethasone sodium phosphate is contraindicated in animals with tuberculosis and chronic nephritis. Existence of congestive heart failure, osteoporosis and diabetes are relative contraindications.

In the presence of infection appropriate antibacterial agents should also be administered and should be continued for at least 3 days after discontinuance of the hormone and disappearance of all signs of infection.

WARNINGS

Clinical and experimental data have demonstrated that corticosteroids administered orally or by injection to animals may induce the first stage of parturition if used during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta and metritis.

Additionally, corticosteroids administered to dogs, rabbits, and rodents during pregnancy have produced cleft palate. Other congenital anomalies including deformed forelegs, phocomelia, and anasarca have been reported in offspring of dogs which received corticosteroids during pregnancy.

PRECAUTIONS

Because of the anti-inflammatory action of corticosteroids, signs of infection may be hidden and it may be necessary to stop treatment until diagnosis is made. Overdosage of some glucocorticoids may result in sodium retention, fluid retention, potassium loss and weight gains.

In infections characterized by overwhelming toxicity, dexamethasone sodium phosphate therapy, in conjunction with indicated antibacterial therapy, is effective in reducing mortality. It is essential that the causative organism be known and an effective antibacterial agent be administered concurrently. The injudicious use of adrenal hormones in animals with infections can be hazardous.

Use of corticosteroids, depending on dose, duration and specific steroid, may result in inhibition of endogenous steroid production following drug withdrawal. In patients presently receiving or recently withdrawn from systemic corticosteroid treatments, therapy with a rapidly acting corticosteroid should be considered in unusually stressful situations.

ADVERSE REACTIONS

The therapeutic use of dexamethasone sodium phosphate injection is unlikely to cause undesired accentuation of metabolic effects. However, if continued corticosteroid therapy is anticipated, a high protein intake should be provided to keep the animal in positive

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nitrogen balance. A retardant effect on wound healing should be considered when it is used in conjunction with surgery. Euphoria or an improvement of attitude, and increased appetite are the usual manifestations.

Side effects such as glycosuria, hyperglycemia, diarrhea, polydipsia and polyuria have been observed in some species.

Side effects such as SAP and SGPT enzyme elevations, eosinopenia, and vomiting have occurred following use of synthetic corticosteroids in dogs.

Cushing's Syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

Corticosteroids reportedly cause laminitis in horses.

CONTACT INFORMATION
To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet (SDS), contact Bimeda, Inc. at 1-888-524-6332. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or online at www.fda.gov.reportanimalae

DOSAGE AND ADMINISTRATION
For Intravenous Use Only.

Horses: The usual intravenous dosage is 2.5 mg to 5 mg (based on 3 mg per mL of dexamethasone content). If permanent corticosteroid effect is required, oral therapy with dexamethasone may be substituted. When therapy is to be withdrawn after prolonged corticosteroid administration, the daily dose should be reduced gradually over a number of days, in stepwise fashion.

HOW SUPPLIED
Dexium-SP™ (dexamethasone sodium phosphate injection) 4 mg/mL (equivalent to 3 mg/mL dexamethasone) is available in 100 mL multiple dose vials.

STORAGE
STORE BETWEEN 15°C - 30°C (56°F - 86°F). PROTECT FROM FREEZING.

Approved by FDA under ANADA # 200-317

List Number	Pack Size	Case Size
1DEX023	100 mL	12

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