Voren™ Suspension

Presentation

Suspension for injection. Each ml contains 1 mg dexamethasone–21-isonicotinate as active ingredient, plus 1.35 mg methyl hydroxybenzoate Ph.Eur and 0.15 mg propyl hydroxybenzoate Ph.Eur (as preservatives).

Uses

Voren Suspension contains a potent long acting corticosteroid with a therapeutic effect lasting for approximately 4 days. Voren Suspension has glucogenic, anti-inflammatory and anti-allergic properties and may be useful in the treatment of a wide range of conditions in cattle, pigs, horses, cats and dogs. For example, acetonaemia (ketosis) in cattle, disease of the locomotor and respiratory system and in inflammatory skin conditions.

Dosage and administration

By intramuscular or intravenous injection. Shake well before use.

Pigs, cattle, calves horses and foals	2 ml/100 kg bodyweight, (i.e. 0.02 mg/kg bodyweight)
Piglets, cats and dogs	1 ml/10 kg bodyweight, (i.e. 0.1 mg/kg bodyweight)

In addition, the subcutaneous route may be used in dogs and cats.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

WITHDRAWAL PERIOD START

Withdrawal Period Information - PLEASE DO NOT REMOVE

Include in WP Book (yes/no)	*Changed since last WP Book (yes/no)*	*Cattle Milk*	*Cattle Meat*	*Sheep Meat*	*Pig Meat*	*Poultry Meat*	*Poultry Eggs*	*Fish Meat*	*Notes*
Yes	Yes	48 hrs	55 days	-	55 days	-	-	-	Not for use in horses intended for human consumption

WITHDRAWAL PERIOD END

Contra-indications, warnings, etc

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

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, 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-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, e.g. dosing on alternative days, 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 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 in long term use. Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis).

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 weaken resistance to or exacerbate existing infections. In the presence of bacterial infection, anti-bacterial 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 g.i.t. ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in corticosteroid-treated animals with spinal cord trauma. Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

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

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

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

For animal treatment only.

Unused product and containers should be disposed of in accordance with any guidance from an appropriate waste regulation authority.

Withdrawal period

Animals must not be slaughtered for human consumption during treatment. Cattle and pigs may be slaughtered for human consumption only after 55 days from the last treatment.

Milk for human consumption must not be taken during treatment. Milk for human consumption may be taken from cattle only after 48 hours (4th milking) from the last treatment.

Not for use in horses intended for human consumption.

Pharmaceutical precautions

Protect from frost. Store below 25°C.

Keep out of the reach of children.

Following withdrawal of the first dose use the product within 28 days after which discard any unused material.

Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, the product should be discarded.

Legal category

POM.

Package quantities

50 ml glass multidose bottles.

Further information

Close veterinary supervision should be maintained during any course of treatment.

Compared with dexamethasone, Voren Suspension has three times the glucogenic effect and seven times the anti-inflammatory effect and comparatively little effect on milk yield when used in lactating cows.

Where longer term treatment is required in horses, dogs and cats, the use of a longer acting dexamethasone product such as Voren 14, (which has a therapeutic effect lasting about 14 days) may be considered.

Marketing authorisation number

VM 00015/4042.