

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Voren Suspension for Injection, 1 mg/ml

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Dexamethasone-21-isonicotinate 1 mg

Methyl hydroxybenzoate 1.35 mg

Propyl hydroxybenzoate 0.15 mg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection.
Fine translucent suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses, pigs, cats and dogs.

4.2 Indications for use,

Ketosis (acetonemia) in cattle. Inflammatory and allergic conditions of the skin, locomotor and respiratory system in cattle, horses, pigs, cats and dogs.

4.3 Contraindications

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

The product is contra indicated for the treatment of "laminitis" in horses where there is a possibility that such treatment could worsen the condition. Additionally it should be noted that the use of the product in horses for other conditions could induce laminitis and careful monitoring should be observed during the treatment period.

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

i. Special precautions for use in animals

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

During a course of treatment the clinical situation should be reviewed frequently.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals

Care should be taken to avoid accidental self injection.

4.6 Adverse reactions (frequency and seriousness)

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 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 alternate 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 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 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.

In very rare cases anaphylactic reactions can occur. These reactions can be fatal.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

G.I.T. ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs.

4.9 Amounts to be administered and administration route

Shake container before use.

The intramuscular route of administration may be used. In addition, the subcutaneous route may be used in dogs and cats.

Cattle, calves, horses and foals:	2 ml/100 kg bodyweight
Pigs:	2 ml/100 kg bodyweight
Piglets:	1 ml/10 kg bodyweight
Cats and dogs:	1 ml/10 kg bodyweight

The veterinary surgeon may wish to reduce the dose for very small patients, i.e. kittens and small puppies. The dose may be repeated once, 4 – 5 days after the initial administration.

Where longer term treatment is necessary, in horses, cats and dogs, a longer acting dexamethasone-21-isonicotinate product which has a therapeutic effect lasting approximately 14 days may be used.

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

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

None known.

4.11 Withdrawal period(s)

Cattle meat : 55 days
Cattle milk : 60 hours

Pig meat : 55 days.

Not to be used in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

5. PHARMACOLOGICAL PROPERTIES

Corticosteroids for systemic use

ATCvet code : QH02AB02

5.1 Pharmacodynamic properties

The product contains a potent long acting corticosteroid with glucogenic, anti-inflammatory and anti-allergic properties and its therapeutic effect lasts for approximately four days.

5.2 Pharmacokinetic particulars

Compared with base dexamethasone, the product has three times the glucogenic effect and seven times the anti-inflammatory effect.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate
Propyl hydroxybenzoate
Sodium Chloride
Polysorbate 80
Water for Injections

6.2 Incompatibilities

None known.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale:
3 years

Shelf life after opening the immediate packaging :
28 days

6.4 Special precautions for storage

Protect from frost. Do not store above 25°C. Following withdrawal of the first dose, use the product within 28 days. Discard unused product. Avoid the introduction of contamination during use. Should any apparent growth or discoloration occur, the product should be discarded.

6.5 Nature and composition of immediate packaging

Cardboard box with one amber glass vial of 50 ml with a bromobutyl bung with aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS

8. MARKETING AUTHORISATION NUMBER

Vm 08327/4321

9. DATE OF FIRST AUTHORISATION

12 October 1994

10. DATE OF REVISION OF THE TEXT

November 2018

Approved: 09 November 2018

