Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Voren Suspension for Injection 1mg/ml

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance

Dexamethasone-21-isonicotinate	1.00	mg

Excipients

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.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, horses, pigs, cats and dogs.

4.2 Indications for use, specifying the target species

Useful in the treatment of a wide range of conditions in cattle, horses, pigs, cats and dogs.
For example, in ketosis (acetonaemia) in cattle, inflammatory skin conditions, disease of the locomotor and respiratory system in cattle, horses, pigs, cats and dogs.

4.3 Contraindications

Do not use in patients with renal disease or diabetes mellitus.

Do not use for the treatment of “laminitis” in horses, where there is the 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 observations during the treatment period should be made.

4.4 Special warnings for each target species

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

4.5 Special precautions for use

Special precaution(s) for use in animals

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

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

None.

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 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-Pituitary-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.
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 would 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 may 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.

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 well before use.
The intramuscular route of administration may be used.

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

In addition, the subcutaneous route may be used in dogs and cats.
Where longer term treatment is necessary, in horses, cats and dogs, a longer acting dexamethasone-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, Pigs and Horses may be slaughtered for human consumption only after 42 days from the last treatment.
Milk for human consumption may be taken from cattle only after 60 hours from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Corticosteroids for systemic use, glucocorticoids
ATCvet Code: QH02AB02

5.1 Pharmacodynamic properties

Compared with base dexamethasone, Voren 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.

5.2 Pharmacokinetic particulars

Voren Suspension contains a potent long acting corticosteroid with a therapeutic effect lasting for approximately 4 days.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl hydroxybenzoate
Propyl hydroxybenzoate
Sodium Chloride
Polysorbate 80Water for Injections

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Protect from frost. Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Cardboard box with one amber glass (Ph. Eur. Type I) multidose vials containing 50 ml. Sealed with bromobutyl rubber stopper and aluminium crimp cap.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Vetmedica GmbH
Binger Strasse 173
55216 Ingelheim am Rhein
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA10454/025/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

May 2018