PARTICULARS TO APPEAR ON THE OUTER PACKAGE

50 ml folding box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Voren Suspension for Injection, 1mg/ml

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 1 mg dexamethasone 21-isonicotinate in an isotonic aqueous suspension.

Contains antimicrobial preservatives:

methyl hydroxybenzoate 1.35 mg/ml

propyl hydroxybenzoate 0.15 mg/ml

3. PHARMACEUTICAL FORM

Veterinary aqueous suspension for injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Cattle, horses, pigs, cats and dogs.

6. INDICATION(S)

Long acting corticosteroid.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Shake container before use.

By intramuscular injection.

Pigs, Cattle, Calves, 2 ml/100 kg bodyweight,

Horses and Foals: (i.e. 0.02 mg/kg bodyweight)

Piglets, 1 ml/10 kg bodyweight,

Cats and Dogs: (i.e. 0.1 mg/kg bodyweight)

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

Reduce the dose for kittens and puppies. The dose may be repeated once 4–5 days after the initial administration. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injection small volumes.

8. WITHDRAWAL PERIOD

Meat: Cattle and Pigs – 55 days

Milk: 60 hours

Animals must not be slaughtered for human consumption during treatment.

Milk for human consumption must not be taken during treatment.

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.

9. SPECIAL WARNING(S), IF NECESSARY

The usual precautions to systemic and local corticosteroid therapy should be observed. NB. For full details of contraindications/warnings, see data sheet/package leaflet.

Not recommended for use in pregnant animals.

Do not use when renal disease or diabetes mellitus is present.

Contraindicated for the treatment of laminitis in horses. May induce laminities in horses being treated for other conditions. In very rare cases anaphylactic reactions can occur. These reactions can be fatal. May cause polyuria, polydipsia, polyphagia, delayed wound healing and adrenal insufficiency. In cases of bacterial infection, antibiotic therapy must be maintained during Voren Suspension treatment.

Gradual withdrawal of treatment is advisable following a prolonged course of administration.

Operator Warnings:

Care should be taken to avoid accidental self injection.

10. EXPIRY DATE

Expiry date:

11. SPECIAL STORAGE CONDITIONS

Protect from frost. Do not store above 25°C. Keep vial in outer carton. Following withdrawal of the first dose, use the product within 28 days, discard any unused material.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

FOR ANIMAL TREATMENT ONLY

To be supplied only on veterinary prescription.

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

16. MARKETING AUTHORISATION NUMBERS

Vm 08327/4321

17. MANUFACTURER'S BATCH NUMBER

Batch No:

18. FURTHER INFORMATION

To be used in accordance with the directions of a veterinary surgeon.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Voren Suspension for Injection, 1mg/ml

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Veterinary aqueous suspension for injection

Each ml contains 1 mg dexamethasone 21-isonicotinate in an isotonic aqueous suspension.

Contains antimicrobial preservatives:

methyl hydroxybenzoate 1.35 mg/ml

propyl hydroxybenzoate 0.15 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

Shake container before use.

By intramuscular injection.

Pigs, Cattle, Calves, 2 ml/100 kg bodyweight,

Horses and Foals: (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.

Reduce the dose for kittens and puppies. The dose may be repeated once 4–5 days after the initial administration. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injection small volumes.

5. WITHDRAWAL PERIOD

Meat – cattle and pigs – 55 days

Milk – cattle – 60 hours

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.

6. BATCH NUMBER

Batch No.:

7. EXPIRY DATE

Expiry Date:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

18. FURTHER INFORMATION

To be used in accordance with the directions of a veterinary surgeon.

Long acting corticosteroid.

Contra-indications, Warnings etc:

The usual precautions to systemic and local corticosteroid therapy should be observed. NB. For full details of contraindications/ warnings, see package leaflet.

Protect from frost. Do not store above 25° C. Keep vial in outer carton.

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.

Operator Warnings:

Care should be taken to avoid self injection.

Disposal Advice:

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

To be supplied only on veterinary prescription.

Keep out of reach and sight of children.

Vm 08327/4321

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

[**Include information under these headings as it appears in the SPC]**

PACKAGE LEAFLET FOR: Voren Suspension for Injection, 1mg/ml

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Voren Suspension for Injection, 1mg/ml

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Sterile injectable white suspension. Each ml contains dexamethasone-isonicotinate

1 mg.

Contains antimicrobial preservatives:

methyl hydroxybenzoate 1.35 mg/ml

propyl hydroxybenzoate 0.15 mg/ml

4. INDICATION(S)

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

Voren Suspension has glucogenic, anti-inflammatory and anti-allergic properties and is indicated for the treatment of acetonaemia (ketosis) in cattle and inflammatory and allergic conditions of the skin, locomotor and respiratory system in cattle, horses, pigs, cats and dogs.

5. CONTRAINDICATIONS

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 HypothalamoPituitreal-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.

Systemic corticosteroid therapy is generally contraindicated in patients with renal disease and diabetes mellitus. 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.

The product is contraindicated for the treatment of laminitis in horses. In very rare cases anaphylactic reactions can occur. These reactions can be fatal.

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.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Cattle, horses, pigs, cats and dogs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Shake container before use.

By intramuscular injection.

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.

Reduce the dose for kittens and puppies, The dose may be repeated once 4 –5 days after the initial administration. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

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 60 hours from the last treatment.

Not to be used in horses 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.

11. SPECIAL STORAGE PRECAUTIONS

Protect from frost. Do not store above 25°C. Following withdrawal of the first dose, use the product within 28 days, discard any unused material.

When the container is broached for the first time, using the in-use shelf life specified on this package insert, the date on which any product remaining should be discarded should be worked out. The discard date should be written on the space provided on the label.

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

12. SPECIAL WARNING(S)

Operator Warnings:

Care should be taken to avoid accidental self injection.

For Animal Treatment Only.

Keep out of the reach and sight of children.

To be used in accordance with the directions of a veterinary surgeon. To be supplied only on veterinary prescription.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Vm 08327/4321

Package Quantities

50 ml glass multidose vials.

Further Information

The veterinary surgeon may wish to reduce the dose of Voren for very small patients, i.e. kittens and small puppies. Close veterinary supervision should be maintained during any course of treatment. After long courses of treatment the dose given should be reduced gradually.

Compared with dexamethasone, Voren Suspension has three times the glucogenic effect and seven times the anti-inflammatory effect. Four-day activity and maintenance of milk yield in the treatment of ketosis. Persistent anti-inflammatory effect in lameness.

Approved: 09 November 2018