Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexamethasone 2mg/ml solution for injection for dogs, cats, cattle and horses

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance		
Dexamethasone	2	mg
(as Dexamethasone sodium phosphate.)		
Excipients		
Sodium Metabisulphite (E223)	1	mg
Methyl Parahydroxybenzoate (E218)	1	mg
Propyl Parahydroxybenzoate (E216)	0.1	mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.
A colourless to almost colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs, Cats, Cattle, Horses

4.2 Indications for use, specifying the target species

Dexamethasone solution is indicated for the treatment of primary bovine ketosis.

Dogs, cats, cattle, horses: as an anti-inflammatory agent. As supportive therapy, dexamethasone may be used in the management of various rheumatic, allergic, dermatologic conditions, and for the treatment of diseases known to be responsive to anti-inflammatory corticosteroids.

4.3 Contraindications

Do not use in animals with diabetes mellitus, osteoporosis, heart disease or kidney disease.
Do not administer to pregnant animals.

4.4 Special warnings for each target species

See 4.3.

4.5 Special precautions for use

Special precautions for use in animals

Animals receiving corticosteroids should be under close observation. Because of the anti-inflammatory action of corticosteroids, signs of infection may be masked and it may be necessary to stop treatment until a further diagnosis is made.

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

Not applicable.

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 Cushingoïd symptoms involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, muscle weakness and osteoporosis may result.

During therapy effective doses suppress the Hypothalamo-Pituitary-Adrenal axis. Following cessation of treatment, symptoms of adrenal insufficiency to adrenocortical atrophy can arise and this may render to deal adequately with stressful situations.

Systematically administered corticoids 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 corticoids have caused deposition of calcium in the skin (calcinosis cutis).

Corticoids 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 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.

Weight loss, anorexia, diarrhoea, polydipsia, and polyuria have occurred following use of synthetic corticosteroids. Vomiting and diarrhoea have been observed in dogs and cats.

Use of this product in horses may induce laminitis and careful assessment should be repeated during the treatment period.

4.7 Use during pregnancy, lactation or lay

Do not adminsiter to pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

By intravenous or intramuscular administration.
To ensure a correct dosage bodyweight should be determined as accurately as possible.
Horse, Cow: 5 - 15 ml (approx. 0.02 mg/kg)
Foal, Calf: 1 - 5 ml (approx. 0.04 mg/kg)
Dog, Cat: 0.25 - 2 ml (approx. 0.1 mg/kg)

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

Overdosage of some glucocorticosteroids may result in sodium retention, fluid retention, potassium loss and weight gain.

4.11 Withdrawal Period(s)

Meat and offal: 28 days
Milk: 5 days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: corticosteroids for systemic use

ATCvet code: QH02AB02

5.1 Pharmacodynamic properties

Dexamethasone is a synthetic glucocorticoid with potent anti-inflammatory properties. The pharmacological properties of dexamethasone are well known in animals.
Parenteral administration of dexamethasone preparations is commonly employed, with the intravenous route causing a prompt but short - lived effect.
The intramuscular route is most commonly employed.

5.2 Pharmacokinetic properties

When given intramuscularly it is known from literature that the phosphate esters are absorbed in minutes to hours. Following absorption into blood, approximately 10 to 15 per cent is not bound.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium Metabisulphite (E223)
Methyl Parahydroxybenzoate (E218)
Propyl Parahydroxybenzoate (E216)
Disodium Phosphate Dodecahydrate
Sodium Dihydrogen Phosphate Dihydrate
Sodium Hydroxide
Glacial Acetic Acid
Water for Injection

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4 Special precautions for storage

Store below 25°C.
Protect from light.
Once opened, store at 2-8°C, protected from light.

6.5 Nature and composition of immediate packaging

100 ml amber vials, glass Type II, with butyl rubber stoppers and non-reusable aluminium closures.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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

7 MARKETING AUTHORISATION HOLDER

Alfasan International B.V.
Kuipersweg 9
3449 JA Woerden
Holland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10980/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT