Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexatat 2 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance	
Dexamethasone	
(as Dexamethasone Sodium Phosphate)	2.0 mg/ml
Excipients	
Chlorocresol	1.0 mg/ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
A clear colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, calves, pigs, dogs, cats and horses.

4.2 Indications for use, specifying the target species

Cattle: Acetonemia.
Cattle, calves, pigs, dogs, cats and horses: shock and stress conditions, allergies, eczema, arthritis, bursitis, tendovaginitis as well as in any case where the antiphlogistic effects of glucocorticoids are desirable. When Dexatat is used in the presence of bacterial infections, appropriate antibacterial therapy should also be instituted.

4.3 Contraindications

Do not use in pregnant animals.
Do not use in viral infections during the viraemic phase.
Diabetes mellitus, osteoporosis, cardiac and renal diseases.
Do not use in horses for the treatment of laminitis.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

None.

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, 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. Consideration should therefore be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment, e.g. dosing to coincide with the time of the endogenous corticosol peak and a gradual reduction of dosage.
Systematically 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 immuno-suppressant 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 gastrointestinal ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in corticosteroid treated animals with spinal and cord trauma. Steroids may cause enlargement of the liver (hepato-megaly) with increased serum hepatic enzymes.
Use of corticosteroids in horses has been reported to induce laminitis. Therefore horses treated with such preparations should be monitored frequently during the treatment period.
A temporary decrease in the milk yield may appear. If administered to pregnant animal, dexamathasone may cause induction of labour in cattle, and retention of placenta.

4.7 Use during pregnancy, lactation or lay

The product is contraindicated in pregnant animals. Corticosteroids are not recommended for the 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. High dosage may lead to a decrease of the milk yield.

4.8 Interaction with other medicinal products and other forms of interaction

A reduced immune response must be anticipated if glucocorticoid treatment is administered shortly before or up to 2 weeks after an active immunisation.

4.9 Amounts to be administered and administration route

The dosage depends on the nature and severity of the disease. In general, the higher dosage rates indicated should be followed in the treatment of acute or severe diseases and for initiating the treatment of chronic conditions. The stated lower dosage rate is generally sufficient for follow-up treatment and in cases of mild disease.

Cattle, Horses : 5 ml to 15 ml (10 mg to 30 mg)
Calves : 1 ml to 2.5 ml (2 mg to 5 mg)
Pigs : 1 ml to 2.5 ml (2 mg to 5 mg)
Dogs : 0.12 ml to 1 ml (0.25 mg to 2 mg)
Cats : 0.12 ml to 0.25 ml (0.25 mg to 0.5 mg)

Cattle, calves and pigs: for intravenous or intramuscular injection.
Horses, dogs and cats: for intramuscular injection.
Depending on the severity of the disease: one or several administrations.

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

See section 4.6 “Adverse reactions”
Antidote is not known.

4.11 Withdrawal Period(s)

Meat and offal:	Cattle	16 days
	Pigs	4 days
	Horses	6 months
Milk:	Cattle	84 hours

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacoterapeutic group: Corticosteroids for systemic use, glucocorticoids
ATCvet code: QH02AB02

5.1 Pharmacodynamic properties

Dexamethasone is a long-acting synthetic analogue of cortisone and belongs to the group of glucocorticoids. Like all glucocorticoids it has an antiphlogistic and anti-allergic action and promotes gluconeogenesis. Thus this mode of action corresponds to that of natural cortisol.

5.2 Pharmacokinetic properties

Following parenteral application Dexamethasone is quickly absorbed and distributed in the body. Glucocortoids are metabolised in the liver and are excreted via the kidneys.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorocresol
Sodium citrate dihydrate
Sodium hydroxide (4% solution)
Citric acid monohydrate
Water for Injections

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: 3 years
Shelf-life after first opening the immediate container: 28 days

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

Vial: 50 ml or 100 ml amber glass vials.
Multipack: 12 x 50 ml, 12 x 100 ml

Not all pack sizes may be marketed.

Stopper: Rubber
Cap: Aluminium Flanging cap

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

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

7 MARKETING AUTHORISATION HOLDER

aniMedica GmbH
Im Sudfeld 9
D-48308 Senden Bosensell
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10826/002/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989
Date of last renewal: 13th March 2009

10 DATE OF REVISION OF THE TEXT

March 2013