1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexatat 2 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:
Dexamethasone 2.0 mg
(as Dexamethasone Sodium Phosphate)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Chlorocresol	1.0 g
Sodium citrate dihydrate	
Sodium hydroxide (4% solution)	
Citric acid monohydrate	
Water for Injections	

A clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs, dogs, cats and horses.

3.2 Indications for use for each target species

Cattle: Acetonemia.
Cattle, 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 the veterinary medicinal product is used in the presence of bacterial infections, appropriate antibacterial therapy should also be instituted.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

None.

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

None.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, pigs, dogs, cats and horses:

Undetermined frequency (cannot be estimated from the available data)	Iatrogenic hyperadrenocorticism (Cushing´s disease)[1], polyuria[2], polydipsia[2], polyphagia[2], sodium retention[3], water retention[3], hypokalaemia[3], cutaneous calcinosis, delayed wound healing, weakened resistance to or exacerbation of existing infections[4], gastrointestinal ulceration[5], hepatomegaly[6], changes in blood biochemical and haematological parameters, laminitis[7], milk production decrease, retained placenta[8], induction of labour[8]

[1] 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.

[2] After systemic administration and particularly during the early stages of therapy.

[3] Upon long-term use.

[4] In the presence of bacterial infection, antibacterial 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.

[5] May be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

[6] Increased serum hepatic enzymes.

[7] In horses. Therefore, horses treated with such preparations should be monitored frequently during the treatment period.

[8] In cattle; if administered to pregnant animal.

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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
The veterinary medicinal 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.

3.8 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.

3.9 Administration routes and dosage

Cattle, calves and pigs: Intravenous or intramuscular use.
Horses, dogs and cats: Intramuscular use.

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 m1 to 15 ml (10 mg to 30 mg)
Calves:	1 ml to 2.5 m1 (2 mg to 5 mg)
Pigs:	1 ml to 2.5 m1 (2 mg to 5 mg)
Dogs:	0.12 ml to 1 m1 (0.25 mg to 2 mg)
Cats:	0.12 ml to 0.25 m1 (0.25 mg to 0.5 mg)

Depending on the severity of the disease: one or several administrations.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

See section 3.6 "Adverse events"
Antidote is not known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle:
Meat and offal: 16 days.
Milk: 84 hours.

Pigs:
Meat and offal: 4 days.

Horses:

Meat and offal: 6 months.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH02AB02

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

Do not store above 25 °C.

5.4 Nature and composition of immediate packaging

Amber glass vial with rubber stopper and aluminium flanging cap in a cardboard box.

Pack sizes:
50 ml
100 ml
12 x 50 ml
12 x 100 ml

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

aniMedica GmbH

7. MARKETING AUTHORISATION NUMBER(S)

VPA10826/002/001

8. DATE OF FIRST AUTHORISATION

01/10/1989

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

26/03/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).