SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexadreson, 2 mg/ml, solution for injection for cattle, horses, pigs, dogs and cats.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Dexamethasone (as sodium phosphate) 2 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol	15.6 mg
Sodium chloride	
Sodium citrate dihydrate	
Sodium hydroxide (for pH adjustment)	
Citric acid (for pH adjustment)	
Water for injections	

Clear, colorless solution for parenteral injection.
pH 7.0-7.8

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, pigs, dogs and cats.

3.2 Indications for use for each target species

Conditions where the glucocorticoids anti-inflammatory, anti-allergical, immunosuppressive or glucogenetic effects are desired.
This veterinary medicinal product gives a rapid effect with short duration.

3.3 Contraindications

Cushing disease. This veterinary medicinal product should not be used during pregnancy's last trimester.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Use with caution if there is suspicion of ulcus ventriculi, diabetes mellitus, corneal ulcer, fungal and virus infections, renal insufficiency or congestive heart failure. If administered concurrently with bacterial infections, antibiotics should be administered as well. Due to dexamethasone's immunosuppressive abilities, concurrent vaccination should be avoided.
Use on young or older individuals, can cause increased risk of side effects. A reduced dose and clinical observation during an eventual treatment is therefore necessary.

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

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigs, dogs and cats:

Rare (1 to 10 animals / 10,000 animals treated):	Other blood disorder (increase in potassium and calcium excretion, sodium and water retention)[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hyperglycaemia[2] Muscle atrophy Delayed healing Skin textural change (atrophy) Hypersensitivity

[1] Dexamethasone may therefore potentiate the effect of a certain kind of heart medicines (cardiac glycosides)
[2] Increased glycogenesis, worsening of diabetes mellitus and latent diabetes mellitus can be manifested

Cattle:

Rare (1 to 10 animals / 10,000 animals treated):	Other blood disorder (increase in potassium and calcium excretion, sodium and water retention)[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hyperglycaemia[2] Muscle atrophy Delayed healing Skin textural change (atrophy) Hypersensitivity Milk production decrease

[1] Dexamethasone may therefore potentiate the effect of a certain kind of heart medicines (cardiac glycosides)
[2] Increased glycogenesis, worsening of diabetes mellitus and latent diabetes mellitus can be manifested

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Other blood disorder (increase in potassium and calcium excretion, sodium and water retention)[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Hyperglycaemia[2] Muscle atrophy Delayed healing Skin textural change (atrophy) Hypersensitivity Laminitis

[1] Dexamethasone may therefore potentiate the effect of a certain kind of heart medicines (cardiac glycosides)

[2] Increased glycogenesis, worsening of diabetes mellitus and latent diabetes mellitus can be manifested

Except from substitution therapy, corticosteroid treatments always include an over dosage compared to the physiological condition. Adverse effects do not always depend on the size of the dose and the length of the treatment, but also on the individuals' sensitivity.
The individuals own hormone (ACTH- and cortisol) excretion is inhibited and cushingoid symptoms can occur. Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal tract ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs.
The immunosuppressant actions may weaken resistance to or exacerbate existing infections.

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:

Administration in early pregnancy may cause fetal abnormalities or delayed fetal growth.
Administration in late pregnancy may cause early parturition or abortion.
Treatment of pregnant animal should be avoided and should only be done according to the responsible veterinarians risk-benefit evaluation.

3.8 Interaction with other medicinal products and other forms of interaction

Dexamethasone should not be given together with other anti-inflammatory drugs. In rare cases, administration of Dexamethasone can lead to hypokalemia, and as such potentiate the effect of cardiac glycosides.
Because corticosteroids can depress the immune response, this veterinary medicinal product should not be used in combination with vaccines.

3.9 Administration routes and dosage

Intramuscular use or slow intravenous infusion.

Species:	Dosage (Intramuscular or slow intravenous infusion)
Horses, cattle	0,06 mg/kg (3 ml/100 kg)
Pigs	0,06 mg/kg (3 ml/100 kg, dosage can be repeated after 24 to 48 hours)
Dog, cat	0,1 mg/kg (0,5 ml/10 kg, dosage can be repeated after 24 to 48 hours)

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

High doses can cause drowsiness and lethargy in horse. When treating with a high dose, thrombosis complications can occur due to increased clotting propensity. See also section 3.6.

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:	8 days
	Milk:	72 hours
Pigs:	Meat and offal:	2 days
Horses:	Meat and offal:	8 days

Not authorized for use in horses producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH02AB02

4.2 Pharmacodynamics

Dexamethasone is a fluoro-methyl derived corticosteroid, with anti-inflammatory, anti-allergenic and immunosuppressive properties. Dexamethasone also stimulates glycogenesis leading to elevated sugar levels. The relative efficacy of dexamethasone graded by the anti-inflammatory effect is about 25 times higher than that of hydrocortisone, while its mineralocorticoid effect is minimal.

4.3 Pharmacokinetics

This veterinary medicinal product contains the sodium phosphate ester of dexamethasone. Following intramuscular injection this soluble ester of dexamethasone is rapidly absorbed at the area of injection and is rapidly hydrolyzed to dexamethasone. In cattle and horse maximum plasma concentration of dexamethasone is achieved within 20 minutes and in pigs and dogs within 10 minutes. The species cat has not been examined. Half time after intravenous and intra muscular injection is similar, varying between 5-20 hours for relevant species. Bio-availability after intra muscular injection is closer to 100%.

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: 8 weeks.

5.3 Special precautions for storage

Do not store above 25° C.
Store the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

20 and 50 ml clear glass (Type I Ph.Eur.) vials, closed with a halogenated butyl rubber stopper and sealed with a coded aluminum cap.
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

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:{DD/MM/YYYY}.

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

2025-07-07

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).