

ANNEX I
SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ES: DEXAVEX 2 mg/ml solution for injection

PT: DEXINJET 2 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Dexamethasone (as Dexamethasone Sodium Phosphate) 2.0 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 (E-1519)	15.6 mg
Sodium citrate (E-331)	
Sodium chloride	
Citric acid	
Sodium hydroxide	
Water for injections	

Colourless clear solution.

3. CLINICAL PARTICULARS

3.1 Target species

Cattle, goats, horses, pigs, dogs and cats

3.2 Indications for use for each target species

Cattle, goats, horses, pigs, dogs and cats:

- Treatment of inflammatory or allergic processes.

Cattle:

- Induction of parturition.
- Treatment of primary ketosis (acetoaemia)

Goats:

- Treatment of primary ketosis (acetoaemia, pregnancy toxemia)

Horses:

- Treatment of arthritis, bursitis or synovitis.

3.3 Contraindications

Except in emergency situations the product should not be used in animals suffering from diabetes, chronic nephritis, renal disease, congestive heart failure, and osteoporosis.

Do not use in viral infections during the viraemic stage or in systemic mycotic infections.

Do not use in animal with gastric or corneal ulcers or in animals with demodicosis.

Do not use by intraarticular injection in case of fractures, bacterial joints infections or bone necrosis.

Do not use in cases of hypersensitivity to the active substance, corticosteroids or to any of the excipients.

See also point 3.7

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Response to long term therapy should be periodically monitored by veterinarian.

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.

Because the pharmacokinetic properties of the active substance, special precautions must be taken when its administration to immune compromised animals.

Corticosteroids treatments may cause Cushing's syndrome.

Administration of corticoids as general, excepting when are used in ketosis or for induction of the parturition produce an improvement in clinical symptoms rather than a cure. The underlying disease should be further investigated.

Following intra-articular administration, use of the joint should be minimized for 4 weeks and surgery on the joint should not be performed within eight weeks of use of this route of administration.

It is recommended not to withdraw abruptly treatment after long term therapies.

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

Dexamethasone and benzyl alcohol may cause allergic reactions. People with known hypersensitivity to dexamethasone, benzyl alcohol or any of the excipients should avoid contact with the veterinary medicinal product.

Care should be taken to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.

Adverse effects on the foetus cannot be excluded. Pregnant women should not handle this product.

This product may be irritant to the skin and eyes. Avoid contact with the skin and eyes. In case of accidental eye or skin contact, rinse with plenty of clean water. If irritation persists, seek medical advice and show the package leaflet or the label to the physician.

Wash hands after use.

3.6 Adverse events

Cattle, goats, horses, pigs, dogs and cats

<p>Very rare (<1 animal / 10,000 animals treated, including isolated reports):</p>	<p>Hyperadrenocorticism¹ (Cushing disease), adrenal gland disorders²</p> <p>Polydipsia³ and polyphagia³, delayed healing</p> <p>Polyuria³</p> <p>Electrolyte disorders (hyponatremia, hypokalaemia)⁴, elevated liver enzymes, hyperglycaemia⁵, other abnormal test result (changes in blood biochemical and haematological parameters)</p> <p>Cutaneous calcinosis</p> <p>Other immune system disorder⁶</p> <p>Gastric ulceration⁷, acute pancreatitis</p> <p>Enlarged liver (hepatomegaly)</p> <p>Retained placenta, metritis, delayed uterine involution, reduced conception rate.</p> <p>Laminitis</p> <p>Milk production decrease</p>
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¹ Iatrogenic. Involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, increase in body fat, increase in body weight, muscle weakness and wastage and osteoporosis.

² During therapy, effective doses suppress the hypothalamo-pituitary-adrenal axis. Following cessation of treatment, signs 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.

³ When systemically administered corticosteroids and particularly during the early stages of therapy.

⁴ In long term use.

⁵ Transient.

⁶ The immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of bacterial infection, concurrent antibacterial therapy is usually required. In the presence of viral infections, corticosteroids may worsen or hasten the progress of the disease.

⁷ Gastrointestinal ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Do not administer the product in pregnant females, except where the intention is to induce parturition. Laboratory animal studies have caused foetal abnormalities in early pregnancy.

Administration in late pregnancy is likely to cause abortion or early parturition in ruminants and may have a similar effect in other species.

Lactation:

Use of the veterinary medicinal product in lactating cows may cause a reduction in milk yield.

3.8 Interaction with other medicinal products and other forms of interaction

Because corticosteroids can reduce the immune response to vaccination, dexamethasone should not be used in combination with vaccines or within two weeks after vaccination.

Concurrent use with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.

Administration of dexamethasone may induce hypokalaemia and hence increase the risk of toxicity from cardiac glycosides. The risk of hypokalaemia may be increased if dexamethasone is administered together with potassium depleting diuretics.

Concurrent use with anticholinesterase may lead to increased muscle weakness in patients with myasthenia gravis.

Glucocorticoids antagonise the effects of insulin.

Concurrent use with phenobarbital, phenytoin and rifampicin can reduce the effects of dexamethasone.

3.9 Administration routes and dosage

Horses: for intravenous, intramuscular or intra-articular administration.

Cattle, pigs, dogs and cats: For intramuscular injection.

Goats: for intravenous or intramuscular injection.

Strict asepsis is essential

To measure small volumes of less than 1 ml a suitably graduated syringe should be used to ensure accurate administration of the correct dose.

For the treatment of inflammatory or allergic conditions the following average doses are advised. However the actual dose used should be determined by the severity of the signs and the length of time for which they have been present.

Species	Dosage
Horses, cattle, goats, pigs	0.06 mg dexamethasone/kg body weight corresponding to 1.5 ml/50 kg
Dog, cat	0.1 mg dexamethasone/kg body weight corresponding to 0.5 ml/10 kg

For the treatment of primary ketosis in cattle (acetonaemia)

It is recommended to administer doses from 0.02 to 0.04 mg dexamethasone/kg body weight corresponding to 5-10 ml per cow given by intramuscular injection dependent on the size of the cow and the duration of the signs. Care should be taken not to overdose Jersey/Guernsey breeds. Larger doses will be required if the signs have been present for some time or if relapsed animals are being treated.

In most cases cure will be obtained with single dose.

For the induction of parturition in cattle

0.04 mg dexamethasone/kg body weight corresponding to 10 ml per cow as a single intramuscular injection after day 260 of pregnancy.

Parturition will normally occur within 48-72 hours.

For the treatment of arthritis, bursitis or tenosynovitis by single intra-articular, injection in the horse

Dosage 1-5 ml

These quantities are not specific and are quoted purely as a guide. Injections into joint spaces or bursae should be preceded by the removal of an equivalent volume of synovial fluid.

The vial cannot be broached more than 50 times

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

An overdose can induce drowsiness and lethargy in horses.

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

ES: Administration by a veterinary surgeon or under their direct responsibility. In case of the intravenous or intra-articular route administration only by veterinary surgeon.

3.12 Withdrawal periods

Cattle and goats	meat and offal: 8 days
	milk: 72 hours
Pig	meat and offal: 2 days
Horse	meat and offal: 8 days.

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH02AB02

4.2 Pharmacodynamics

Dexamethasone, a fluoro-methyl derivative of prednisolone, is a potent glucocorticoid with minimal mineralocorticoid activity. Dexamethasone has ten to twenty times the anti-inflammatory activity of prednisolone. Is characterized by a short and prompt pharmacological action.

4.3 Pharmacokinetics

Following parenteral injection dexamethasone is readily absorbed and reaching the maximum plasmatic concentration in horses, cattle, goats, pigs and dogs in within 20 minutes following intramuscular administration. Bioavailability after intramuscular administration is almost 100%. Elimination half-life varies per species between 5 and 20 hours. Dexamethasone has a medium duration of activity.

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: 2 years

Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Colourless polypropylene vials of 50 ml closed with bromobutyl rubber closures and aluminium capsules with flip-off sealing.

Pack sizes:

A cardboard box with 1 vial of 50 ml

A cardboard box with 10 vials of 50 ml

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal product 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. MARKETING AUTHORISATION HOLDER

SP VETERINARIA S.A.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 15/01/2013

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

DD/MM/YYYY

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 \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).