ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

[Version 9.1,11/2024]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CALIERCORTIN 4 mg/ml solution for injection for cattle, pigs, horses, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
4 mg of dexamethasone 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**
Benzyl alcohol (E 1519)	9.45 mg
Propylene glycol	
Sodium citrate	
Potassium dihydrogenphosphate	
Water for injection	

Clear and colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, horses, pigs, dogs and cats

3.2 Indications for use for each target species

For palliative (supportive) treatment of the following diseases:
- primary ketoses,
- acute, non-infectious arthritis, tendovaginitis and bursitis
- non-infectious inflammatory or allergic skin diseases.

3.3 Contraindications

Do not use in:

- existing gastrointestinal ulcers, badly healing wounds and ulcers, fractures
- systemic viral infections
- general immunodeficiency
- glaucoma, cataract
- osteoporosis, hypocalcemia
- hypercorticism
- hypertension
- pancreatitis
- in cattle in the last third of gestation
- systemic mycosis

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

3.4 Special warnings

For vaccinations, an appropriate interval between treatment with glucocorticoids should be maintained. Active immunization should not be performed during and up to 2 weeks after glucocorticoid therapy. The formation of sufficient immunity can also be impaired in the case of protective inoculations, which have taken place up to 8 weeks before the start of therapy.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Existing bacterial and parasitic infections need to be eliminated with a suitable treatment before treatment with the product is initiated.

Because of the content of propylene glycol, life-threatening shock reactions can occur in a few cases. The injection solution should therefore be slowly administered and approximately have body temperature. At the first signs of intolerance, the injection should be stopped and, if necessary, a shock treatment should be initiated.

Treatment with glucocorticoids such as the veterinary medicinal product may lead to a severe course of infection. In case of infections the treating veterinarian is to be consulted.

When using dexamethasone, the indication should always be carefully checked.

Relative contraindications that require special precautions are:

- Diabetes mellitus (control of blood values and, if necessary, increase in insulin dose)
- congestive heart failure (careful monitoring)
- chronic renal insufficiency (careful monitoring)
- epilepsy (avoid long term therapy)

The use of glucocorticoids should only be performed after a strict indication in:
- animals in growth and old animals
- suckling animals
- pregnant animals, due to the not sufficiently clarified, possible teratogenic effect of dexamethasone
- in equine, since glucocorticoid induced laminitis can occur as a complication.

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

People with known hypersensitivity to dexamethasone and benzyl alcohol should avoid contact with the veterinary medicinal product.

Corticosteroids can cause foetal malformations; therefore, the veterinary medicinal product should not be administered by pregnant women.
In case of accidental self-injection, seek immediately medical advice and show the package leaflet or the label to the physician.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, horses, pigs, dogs and cats

Rare (1 to 10 animals / 10 000 animals treated):	Hypersensitivity reaction
Undetermined frequency (cannot be estimated from the available data)	Cushing's syndrome[1], Diabetes mellitus[2], Polyuria[3], Polydipsia[3], Polyphagia[3] Cutaneous calcinosis Electrolyte disorder (Sodium retention, Water retention, Hypokalaemia)[4] Thrombosis[5] Adrenal gland disorder[6] Euphoric effect, Excitation, Lowering of the convulsive threshold, Epilepsy[7] Skin thinning Delayed healing[8] Immunosuppression[9], Arthropathy, Ulceration[10] Hepatomegaly, Elevated liver enzymes Retained placenta[11], Metritis[12], Subfertility[12] Acute pancreatitis[13] Aggression[14] Depression[14,15] Hypertension, Oedema, Hypocalcaemia Reduced growth rate [16] Glaucoma, Cataract Muscle weakness Osteoporosis

[1] involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat and wastage may result
[2] combined with reduced glucose tolerance, steroid induced or deterioration of existing diabetes mellitus
[3] during the early stages of therapy
[4] In long term use
[5] increased risk
[6] reversible inactivity atrophy of the suprarenal gland due to steroid induced ACTH suppression
[7] Manifestation of latent epsilepsy
[8] of wounds and bone
[9] weakened resistance to or exacerbate existing infections
[10] in the gastrointestinal tract, may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma
[11] when used for induction of parturition in cattle
[12] possible aftereffect when used for induction of parturition in cattle
[13] increased risk
[14] in dogs
[15] In cats
[16] growth retardation with disruptive bone growth and damage of bone matrix

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:

Due to the fact that the teratogenic effect of dexamethasone is not sufficiently understood, application during pregnancy should only be carried out with a strict indication.
Do not use in cattle in the last third of pregnancy.

Lactation:

When used during lactation, there is a temporary reduction in milk yield.
In the case of nursing animals, use only after a strict indication since glucocorticoids pass into the milk and growth disturbances on the young animals can occur.

3.8 Interaction with other medicinal products and other forms of interaction

- Decreased cardiac glycoside tolerance due to potassium deficiency.
- Increased potassium losses while concomitant administration of thiazide and grinding diuretics.
- Increased risk of gastrointestinal ulcers and gastrointestinal bleeding with concomitant administration of nonsteroidal antiphlogistics.
- Decreased effect of insulin.
- Decreased glucocorticoid activity when enzyme-inducing drugs are administered.(e.g. barbiturates)
- Increased eye pressure when combined with anticholinergics.
- Reduced effect of anticoagulants.
- Suppression of skin reactions during intracutaneous allergy tests.
- Pronounced muscle weakness in patients with myastenia gravis with concomitant administration of anticholinergics (e.g. neostigmin).

3.9 Administration routes and dosage

For subcutaneous, intramuscular and intravenous use.

Species	**Dosage**
Horses and cattle	0.02–0.06 mg dexamethasone/kg bodyweight equivalent to 0.25 – 0.75 ml veterinary medicinal product for 50 kg bodyweight.
Pigs	0.04 – 0.06 mg dexamethasone/kg bodyweight equivalent to 0.1 – 0.15 ml veterinary medicinal product for 10 kg bodyweight.
Dogs and cats	0.1 – 0.25 mg dexamethasone/kg bodyweight equivalent to 0.025 – 0.063 ml veterinary medicinal product for kg bodyweight.

For single use.

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

Overdoses are associated with increased side effects. An antidote for the veterinary medicinal product is unknown.

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

For administration only by a veterinarian

3.12 Withdrawal periods

Cattle:
Meat and offal: 16 days
Milk: 4 days
Pigs:
Meat and offal: 4 days
Horses:
Meat and offal: 16 days

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH02AB02

4.2 Pharmacodynamics

Dexamethasone belongs to the synthetic glucocorticoids. It is formed by the introduction of a second double bond between positions 1 and 2 in the A ring of cortisol and by fluorination in the 9α position as well as methylation in the 16α position. Compared to the cortisol synthesized in the organism, dexamethasone is 25-30 times more glucocorticoidally effective than cortisol, while the mineral corticoid effects are very low.
Dexamethasone inhibits ACTH synthesis in hypothalamic-pituitary control (negative feedback), which inhibits cortisol secretion in the adrenal gland and can lead to adrenal insufficiency.
Its pharmacological properties unfold dexamethasone after passive absorption into the cells. Dexamethasone acts mainly after binding to a cytoplasmic receptor and translocation in the cell nucleus, from which it affects the protein synthesis of the cell by affecting the transcription and formation of specific mRNA.
In general, dexamethasone, like all glucocorticoids, has effects on carbohydrate (increase in gluconeogenesis), protein (mobilization of amino acids by catabolic metabolic processes) and fat metabolism (fat redistribution), as well as anti-inflammatory, antiallergic, membrane-stabilizing and immunosuppressive qualities.

4.3 Pharmacokinetics

In the body, dexamethasone-21-dihydrogenphosphate disodium is hydrolyzed by esterases so that the pharmacologically active component of the molecule - the free alcohol dexamethasone - is released. Dexamethasone is approximately 70% bound to plasma proteins. The distribution volume of 1.2 l / kg in cattle and dogs shows the good tissue penetration of dexamethasone. The blood / brain barrier is easily passed by dexamethasone, and the placenta is differently treated according to the animal species. Small amounts also enter the milk.

Dexamethasone is predominantly metabolised in the liver into various metabolites which, after reduction of a keto group, are conjugated with sulfuric acid or glucoronic acid mainly via the kidney and to a lesser extent via the bile. Small quantities are also excreted unchanged.
Due to its biological half-life of more than 36 hours, dexamethasone is one of the long-acting glucocorticoids.

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: 7 days

5.3. Special precautions for storage

Store below 30ºC.
Do not freeze.

After first opening the immediate packaging: Store in the refrigerator (2ºC – 8ºC).

5.4 Nature and composition of immediate packaging

Amber glass type I vials of 10 ml with a grey rubber stopper and aluminium capsules with a blue FLIP-OFF ring. Each vial is packed in unitary cardboard box or in a clinical container.

Amber glass type II vials of 50 ml with a grey rubber stopper and aluminium capsules with a blue FLIP-OFF ring. Each vial is packed in unitary cardboard box.

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. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A.

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

{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*).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

[Version 9.1,11/2024]

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CALIERCORTIN 4 mg/ml solution for injection for cattle, pigs, horses, dogs and cats

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Dexamethasone .....4.00 mg
(as dexamethasone sodium phosphate)

3. PACKAGE SIZE

10 ml
50 ml

4. TARGET SPECIES

Cattle, horses, pigs, dogs and cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For subcutaneous, intramuscular and intravenous use

7. WITHDRAWAL PERIODS

Withdrawal periods:
Cattle:
Meat and offal: 16 days
Milk: 4 days
Pigs:
Meat and offal: 4 days
Horses:
Meat and offal: 16 days

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

8. EXPIRY DATE

Exp {mm/yyyy}
Once broached, use within 7 days, use by ….

9. SPECIAL STORAGE PRECAUTIONS

Store below 30ºC.
Do not freeze.
After first opening the immediate packaging: Store in the refrigerator (2ºC – 8ºC)

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

[Version 9.1,11/2024]

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

CALIERCORTIN 4 mg/ml solution for injection for cattle, pigs, horses, dogs and cats

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:

Dexamethasone .....4.00 mg
(as dexamethasone sodium phosphate)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

Once broached, use within 7 days

B. PACKAGE LEAFLET

[Version 9.1,11/2024]

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

CALIERCORTIN 4 mg/ml solution for injection for cattle, pigs, horses, dogs and cats

2. Composition

Each ml contains:

Active substance:
Dexamethasone .....4.00 mg
(as dexamethasone sodium phosphate)

Excipients:
Benzyl alcohol .....9.45 ml

Clear, colorless solution.

3. Target species

Cattle, horses, pigs, dogs and cats

4. Indications for use

For palliative (supportive) treatment of the following diseases:
- primary ketoses,
- acute, non-infectious arthritis, tendovaginitis and bursitis
- non-infectious inflammatory or allergic skin diseases.

5. Contraindications

Do not use in:
- existing gastrointestinal ulcers, badly healing wounds and ulcers, fractures
- systemic viral infections
- general immunodeficiency
- glaucoma, cataract
- osteoporosis, hypocalcemia
- hypercorticism
- hypertension
- pancreatitis
- in cattle in the last third of gestation
- systemic mycosis

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

6. Special warnings

Special warnings

For vaccinations, an appropriate interval between treatment with glucocorticoids should be maintained. Active immunization should not be performed during and up to 2 weeks after glucocorticoid therapy.

The formation of sufficient immunity can also be impaired in the case of protective inoculations, which have taken place up to 8 weeks before the start of therapy.

Special precautions for safe use in the target species:

Existing bacterial and parasitic infections need to be eliminated with a suitable treatment before treatment with the product is initiated.

Because of the content of propylene glycol, life-threatening shock reactions can occur in a few cases. The injection solution should therefore be slowly administered and approximately have body temperature. At the first signs of intolerance, the injection should be stopped and, if necessary, a shock treatment should be initiated.

Treatment with glucocorticoids such as the veterinary medicinal product may lead to a severe course of infection. In case of infections the treating veterinarian is to be consulted.

Relative contraindications that require special precautions are:

- Diabetes mellitus (control of blood values and, if necessary, increase in insulin dose)
- congestive heart failure (careful monitoring)
- chronic renal insufficiency (careful monitoring)
- epilepsy (avoid long term therapy)

The use of glucocorticoids should only be performed after a strict indication in:
- animals in growth and old animals
- suckling animals
- pregnant animals, due to the not sufficiently clarified, possible teratogenic effect of dexamethasone
- in equine, since glucocorticoid induced laminitis can occur as a complication.

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

People with known hypersensitivity to dexamethasone and benzyl alcohol should avoid contact with the product.

Corticosteroids can cause foetal malformations; therefore, the veterinary medicinal product should not be administered by pregnant women.
In case of accidental self-injection, seek medical advice and show the package leaflet or the label to the physician.

Wash hands after use.

Special precautions for the protection of the environment:

Not applicable.

Pregnancy:

Due to the fact that the teratogenic effect of dexamethasone is not sufficiently understood, application during pregnancy should only be carried out with a strict indication.
Do not use in cattle in the last third of pregnancy.

Lactation:

When used during lactation, there is a temporary reduction in milk yield.

In the case of nursing animals, use only after a strict indication since glucocorticoids pass into the milk and growth disturbances on the young animals can occur.

Interaction with other medicinal products and other forms of interaction

- Decreased cardiac glycoside tolerance due to potassium deficiency.
- Increased potassium losses while concomitant administration of thiazide and grinding diuretics.
- Increased risk of gastrointestinal ulcers and gastrointestinal bleeding with concomitant administration of nonsteroidal antiphlogistics.
- Decreased effect of insulin.
- Decreased glucocorticoid activity when enzyme-inducing drugs are administered.
(e.g. barbiturates)
- Increased eye pressure when combined with anticholinergics.
- Reduced effect of anticoagulants.
- Suppression of skin reactions during intracutaneous allergy tests.
- Pronounced muscle weakness in patients with myastenia gravis with concomitant administration of anticholinergics (e.g. neostigmin).

Overdose

Overdoses are associated with increased side effects. An antidote for the veterinary medicinal product is unknown

Special restrictions for use and special conditions for use

For administration only by a veterinarian

Major Incompatibilities

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

7. Adverse events

Cattle, horses, pigs, dogs and cats:

Rare (1 to 10 animals / 10 000 animals treated):	Hypersensitivity reaction
Undetermined frequency (cannot be estimated from the available data)	Cushing's syndrome[1], Diabetes mellitus[2], Polyuria[3], Polydipsia[3], Polyphagia[3] Cutaneous calcinosis Electrolyte disorder (Sodium retention, Water retention, Hypokalaemia)[4] Thrombosis[5] Adrenal gland disorder[6] Euphoric effect, Excitation, Lowering of the convulsive threshold, Epilepsy[7] Skin thinning Delayed healing[8] Immunosuppression[9], Arthropathy, Ulceration[10] Hepatomegaly, Elevated liver enzymes Retained placenta[11], Metritis[12], Subfertility[12] Acute pancreatitis[13] Aggression[14] Depression[14,15] Hypertension, Oedema, Hypocalcaemia Reduced growth rate [16] Glaucoma, Cataract Muscle weakness Osteoporosis

[1] involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat and wastage may result
[2] combined with reduced glucose tolerance, steroid induced or deterioration of existing diabetes mellitus
[3] during the early stages of therapy
[4] In long term use
[5] increased risk
[6] reversible inactivity atrophy of the suprarenal gland due to steroid induced ACTH suppression
[7] Manifestation of latent epsilepsy
[8] of wounds and bone
[9] weakened resistance to or exacerbate existing infections
[10] in the gastrointestinal tract, may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma
[11] when used for induction of parturition in cattle
[12] possible aftereffect when used for induction of parturition in cattle
[13] increased risk
[14] in dogs
[15] In cats
[16] growth retardation with disruptive bone growth and damage of bone matrix

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {*national system details*}

8. Dosage for each species, routes and method of administration

For subcutaneous, intramuscular and intravenous use

Species	Dosage
Horses and cattle	0.02–0.06 mg dexamethasone/kg bodyweight equivalent to 0.25 – 0.75 ml veterinary medicinal product for 50 kg bodyweight.
Pigs	0.04 – 0.06 mg dexamethasone/kg bodyweight equivalent to 0.1 – 0.15 ml veterinary medicinal product for 10 kg bodyweight.
Dogs and cats	0.1 – 0.25 mg dexamethasone/kg bodyweight equivalent to 0.025 – 0.063 ml veterinary medicinal product for kg bodyweight.

For single use.

9. Advice on correct administration

Do not use the veterinary medicinal product if you notice visible signs of deterioration.

10. Withdrawal periods

Cattle:
Meat and offal: 16 days
Milk: 4 days
Pigs:
Meat and offal: 4 days
Horses:
Meat and offal: 16 days

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

11. Special storage precautions

Keep out of the sight and reach of children.

Store below 30ºC.
Do not freeze.
After first opening the immediate packaging: store in a refrigerator (2ºC – 8ºC)

Do not use this veterinary medicinal product after the expiry date which is stated on the label of the vial and the outer carton after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 7 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing Authorisation numbers and pack sizes

Amber glass type I vials of 10 ml with a grey rubber stopper and aluminium capsules with a blue FLIP-OFF ring. Each vial is packed in unitary cardboard box or in a clinical container.

Amber glass type II vials of 50 ml with a grey rubber stopper and aluminium capsules with a blue FLIP-OFF ring. Each vial is packed in unitary cardboard box.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse events:

Laboratorios Calier, S.A.
C/ Barcelonès, 26
Polígono Industrial El Ramassar
08520 Les Franqueses del Vallès
Barcelona
Spain
Tel: +34 938 495 133
E-mail: pharmacovigilance@calier.es

17. Other Information