[Version 8.2,01/2021]

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:
Benzyl alcohol (E-1519) 15.6 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Colourless clear solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses, pigs, dogs and cats

4.2 Indications for use, specifying the target species

Cattle, horses, pigs, dogs and cats:
- Treatment of inflammatory or allergic processes.

Cattle:
- Induction of parturition.
- Treatment of primary ketosis (acetonaemia)

Horses:
- Treatment of arthritis, bursitis or synovitis.

4.3 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 4.7

4.4 Special warnings for each target species

None known.

4.5 Special precautions for use

Special precautions for use in animals

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

People with known hypersensitivity to dexamethasone 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.
Wash hands after use.
Pregnant women should not handle this product.

4.6 Adverse reactions (frequency and seriousness)

Very rarely, corticosteorids can cause the following adverse reactions during treatment:

- Steroids, during treatment, may cause iatrogenic hyperadrenocorticism (Cushing's disease) involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, increase in body weight, muscle weakness and wastage and osteoporosis may result.

- During therapy effective doses suppress the hypothalamo-pituitreal 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.

- Systemically 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).

- Corticosteroid use may delay wound healing and 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.

- Gastrointestinal ulceration has been reported in animals treated with corticosteroids and g.i.t. ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

- Corticosteroid use may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes and may increase the risk of acute pancreatitis.

- Other possible adverse reactions associated with corticosteroid use include retained placenta, metritis, subfertility, laminitis, reduction in milk yield, changes in blood biochemical and haematological parameters.

- Transient hyperglycaemia can occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Do not administer the product in pregnant females, except where the intention is to induce parturition. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy is likely to cause abortion or early parturition in ruminants and may have a similar effect in other species.
Use of the veterinary medicinal product in lactating cows may cause a reduction in milk yield.

4.8 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 anticholinestaerase 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.

4.9 Amounts to be administered and administration route

Horses: for intravenous, intramuscular or intra-articular administration.
Cattle, pigs, dogs and cats: For 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, pigs	0.06 mg dexametasone/kg body weight corresponding to 1.5 ml/50 kg
Dog, cat	0.1 mg dexametasone/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 dexametasone/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 -
0.04 mg dexametasone/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

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

An overdose can induce drowsiness and lethargy in horses.

4.11 Withdrawal period(s)

Cattle	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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: corticosteroid for systemic use.
ATCvet code: QH02AB02

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic particulars

Following parenteral injection dexamethasone is readily absorbed and reaching the maximum plasmatic concentration in horses, cattle, 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E-1519)
Sodium citrate (E-331)
Sodium chloride
Citric acid (for pH adjustment)
Sodium hydroxide (for pH adjustment)
Water for injections

6.2 Major 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: 2 years
Shelf life after first opening the immediate packaging: 28 days

6.4. Special precautions for storage

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

6.5 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.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

SP VETERINARIA S.A.
Ctra Reus Vinyols km 4.1
Riudoms (43330)
SPAIN

8. MARKETING AUTHORISATION NUMBER(S)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:15/01/2013
Date of last renewal:

10 DATE OF REVISION OF THE TEXT

12/12/2013

PROHIBITION OF SALE, SUPPLY AND/OR USE

ES: To be supplied only on veterinary prescription.
Administration by a veterinary surgeon or under their direct responsibility. In case of the intravenous route administration only by veterinary surgeon.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

50 ml box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ES: DEXAVEX 2 mg/ml solution for injection
PT: DEXINJET 2 mg/ml solution for injection
Dexamethasone

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Active substance
Dexamethasone (as Dexamethasone Sodium Phosphate) 2 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

1 vial 50 ml
10 vials 50 ml

5. TARGET SPECIES

Cattle, horses, pigs, dogs and cats

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle 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.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days
Use by …

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton in order to protect from light.
The vial cannot be broached more than 50 times

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

SP VETERINARIA S.A.
Ctra Reus Vinyols km 4.1
Riudoms (43330)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER'S BATCH NUMBER

Lot{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ES: DEXAVEX 2 mg/ml solution for injection
PT: DEXINJET 2 mg/ml solution for injection
Dexamethasone

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

2 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

Horses: for IV, IM or intra-articular administration.
Cattle, pigs, dogs and cats: For IM injection.

5. WITHDRAWAL PERIOD

Withdrawal period:

Cattle	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.

6. BATCH NUMBER

Lot{number}

7. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days
Use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
ES: DEXAVEX 2 mg/ml solution for injection
PT: DEXINJET 2 mg/ml solution for injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
SP VETERINARIA S.A.
Ctra Reus Vinyols km 4.1
Riudoms (43330)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ES: DEXAVEX 2 mg/ml solution for injection
PT: DEXINJET 2 mg/ml solution for injection
Dexamethasone

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:
Dexamethasone (as Dexamethasone Sodium Phosphate) 2 mg

Excipients:
Benzyl alcohol (E-1519) 15.6 mg

Colourless clear solution

4. INDICATION(S)

Cattle, horses, pigs, dogs and cats:
- Treatment of inflammatory or allergic processes.

Cattle:
- Induction of parturition.
- Treatment of primary ketosis (acetonaemia)

Horses:
Treatment of arthritis, bursitis or synovitis

5. 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.

6. ADVERSE REACTIONS

Very rarely, corticosteorids can cause the following adverse reactions during treatment:

- Steroids, during treatment, may cause iatrogenic hyperadrenocorticism (Cushing's disease) involving significant alteration of fat, carbohydrate, protein and mineral metabolism, e.g. redistribution of body fat, increase in body weight, muscle weakness and wastage and osteoporosis may result.

- During therapy effective doses suppress the hypothalamo-pituitreal 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

- Systemically 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).

- Corticosteroid use may delay wound healing and 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.

- Gastrointestinal ulceration has been reported in animals treated with corticosteroids and g.i.t. ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.

- Corticosteroid use may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes and may increase the risk of acute pancreatitis.

- Other possible adverse reactions associated with corticosteroid use include retained placenta, metritis, subfertility, laminitis, reduction in milk yield, changes in blood biochemical and haematological parameters.

- Transient hyperglycaemia can occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
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- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, horses, pigs, dogs and cats

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Horses: for intravenous, intramuscular or intra-articular administration.
Cattle, pigs, dogs and cats: For 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, pigs	0.06 mg dexametasone/kg body weight corresponding to 1.5 ml/50 kg
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For the treatment of primary ketosis in cattle (acetonaemia)
It is recommended to administer doses from 0.02 to 0.04 mg dexametasone /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 -
0.04 mg dexametasone /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, l 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

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD(S)

Cattle 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.

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

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 28 days

12. SPECIAL WARNING(S)

Special precautions for use in animals

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

People with known hypersensitivity to the active substance 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 to the physician.
Wash hands after use.
Pregnant women should not handle this product.

Pregnancy:
Do not administer the product in pregnant females, except where the intention is to induce parturition. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. 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.

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 anticholinestaerase 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.

Overdose (symptoms, emergency procedures, antidotes):
An overdose can induce drowsiness and lethargy in horses.

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

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.