ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Label, vial}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafast 2 mg/ml solution for injection for horses, cattle, pigs, dogs and cats
dexamethasone

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substance:
Dexamethasone 2.0 mg
(as dexamethasone sodium phosphate)

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml,
100 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs, 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 period(s):

Meat and offal:
Cattle: 8 days.
Pigs: 2 days.
Horses: 8 days.

Milk:
Cattle: 72 hours.

Horses: Not authorised for use in horses producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}

Shelf-life after first opening of the immediate packaging: 28 days
Once opened use by……

11. SPECIAL STORAGE CONDITIONS

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

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

LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43173/4009

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{Label, 20 ml}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafast 2 mg/ml solution for injection for horses, cattle, pigs, dogs and cats
dexamethasone

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 ml contains:

Active substance:
Dexamethasone 2.0 mg
(as dexamethasone sodium phosphate)

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

20 ml

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):

Meat and offal:
Cattle: 8 days.
Pigs: 2 days.
Horses: 8 days.

Milk:
Cattle: 72 hours.
Horses: Not authorised for use in horses producing milk for human consumption

6. BATCH NUMBER

Batch{number}

7. EXPIRY DATE

EXP {month/year}

Shelf-life after first opening of the immediate packaging: 28 days
Once opened use by……

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafast 2 mg/ml solution for injection for horses, cattle, pigs, dogs and cats
dexamethasone

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:

Active substance:
Dexamethasone 2.0 mg
(as dexamethasone sodium phosphate)

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

1 x 20 ml, 6 x 20 ml, 12 x 20 ml
1 x 50 ml, 6 x 50 ml, 12 x 50 ml
1 x 100 ml, 6 x 100 ml, 12 x 100 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs, 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 period(s):

Meat and offal:
Cattle: 8 days.
Pigs: 2 days.
Horses: 8 days.

Milk:

Cattle: 72 hours.
Horses: Not authorised for use in horses producing milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first opening of the immediate packaging: 28 days

11. SPECIAL STORAGE CONDITIONS

Protect from light.

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

LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 43173/4009

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

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

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

Marketing authorisation holder:
LIVISTO Int'l, S.L.
Av. Universitat Autònoma, 29
08290 Cerdanyola del Vallès (Barcelona)
Spain

Manufacturer responsible for batch release:
aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

aniMedica Herstellungs GmbH
Im Südfeld 9
48308 Senden-Bösensell
Germany

Industrial Veterinaria, S.A.
Esmeralda 19
Esplugues de Llobregat
08950 Barcelona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafast 2 mg/ml solution for injection for horses, cattle, pigs, dogs and cats
Dexamethasone

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

1 ml contains:

Active substance:

Dexamethasone (as dexamethasone sodium phosphate)	2.0 mg

Excipient:

Benzyl alcohol (E1519)	15.6 mg

Clear, colourless solution.

4. INDICATION(S)

Horses, cattle, pigs, dogs and cats:
Treatment of inflammatory or allergic conditions.

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

Horses:
Treatment of arthritis, bursitis or tenosynovitis.

5. CONTRAINDICATIONS

Except in emergency situations, do not use in animals suffering from diabetes mellitus, renal insufficiency, cardiac insufficiency, hyperadrenocorticism or osteoporosis.
Do not use in viral infections during the viraemic stage or in cases of systemic mycotic infections.
Do not use in animals suffering from gastrointestinal or corneal ulcers, or demodicosis.
Do not administer intra-articularly where there is evidence of fractures, bacterial joint infections and aseptic bone necrosis.
Do not use in known cases of hypersensitivity to the active substance, to corticosteroids and to any other ingredient of the product.
See also section "Pregnancy and lactation".

6. ADVERSE REACTIONS

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. During medium to long term use the dose should therefore generally be kept to the minimum necessary to control symptoms.

Steroids themselves, 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, muscle weakness and wastage and osteoporosis may result.

During therapy effective doses suppress the hypothalamo-pituitreal-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 (for further discussion see standard texts).

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 upon long term use. Systemic corticosteroids have caused deposition of calcium in the skin (calcinosis cutis).

Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. 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.

Gastrointestinal ulceration has been reported in animals treated with corticosteroids and gastrointestinal ulceration may be exacerbated by steroids in patients given non-

steroidal anti-inflammatory drugs and in animals with spinal cord trauma. Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

Corticosteroid use may induce changes in blood biochemical and haematological parameters. Transient hyperglycaemia can occur.
If the product is used for induction of parturition in cattle, then a high incidence of retained placentae may be experienced and possible subsequent metritis and/or subfertility. Such use of dexamethasone, particularly at early time points, may be associated with reduced viability of the calf.

Corticosteroid use may increase the risk of acute pancreatitis. Other possible adverse reactions associated with corticosteroid use include laminitis and reduction in milk yield.

In very rare cases, hypersensitivity reactions may occur.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reactions during the course of one treatment)
- 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).

7. TARGET SPECIES

Horses, cattle, pigs, dogs and cats.

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

Routes of administration:

Horses:	Intravenous, intramuscular or intra-articular injection.
Cattle, pigs, dogs and cats:	Intramuscular injection.

Use normal aseptic techniques.
To measure small volumes of less than 1 ml of the product, 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 doses are advised.

Species	**Dosage**
Horses, cattle, pigs	0.06 mg dexamethasone /kg body weight corresponding to 1.5 ml/50 kg
Dogs, cats	0.1 mg dexamethasone /kg body weight corresponding to 0.5 ml/10 kg

For the treatment of primary ketosis in cattle (acetonaemia): 0.02 to 0.04 mg dexamethasone /kg body weight corresponding to a dose of 5-10 ml of the product per 500 kg BW given by intramuscular injection is advocated dependent on the size

of the cow and the duration of the signs. Care should be taken not to overdose Channel Island breeds. Larger doses (up to 0.06 mg dexamethasone/kg) will be required if the signs have been present for some time or if relapsed animals are being treated.

For the induction of parturition - to avoid foetal oversize and mammary oedema in cattle. A single intramuscular injection of 0.04 mg dexamethasone /kg body weight corresponding to 10 ml of the product per 500 kg BW after day 260 of pregnancy.
Parturition will normally occur within 48 – 72 hours.

For the treatment of arthritis, bursitis or tenosynovitis by intra-articular injection in horses:
Dose 1 – 5 ml of the product.
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. Strict asepsis is essential.

The cap may be safely punctured up to 100 times.
Please select the most appropriate vial size according to the target species to be treated.

When treating groups of animals, use a draw-off needle to avoid excessive broaching of the stopper. The draw-off needle should be removed after treatment.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable

10. WITHDRAWAL PERIOD(S)

Meat and offal:
Cattle: 8 days.
Pigs: 2 days.
Horses: 8 days.

Milk:
Cattle: 72 hours.
Horses: 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.

Shelf life after first opening the container: 28 days
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in

the vial should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNINGS

Special warnings for each target species:
None.

Special precautions for use in animals:
Response to long-term therapy should be monitored at regular intervals by a veterinary surgeon. 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 of the pharmacological properties of the active ingredient, special care should be taken when the product is used in animals with a weakened immune system.

Except in cases of acetonaemia and induction of parturition, the purpose of corticosteroid administration is to produce an improvement in clinical signs rather than a cure. The underlying disease should be further investigated. Following intra-articular administration, use of the joint should be minimized for one month and surgery on the joint should not be performed within eight weeks of use of this route of administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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 doctor.
Pregnant women should not handle this veterinary medicinal product.
Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash the area thoroughly with clean running water.
People with known hypersensitivity to the active substance or any of the excipients should avoid contact with the product.
Wash hands after use.

Pregnancy and lactation:
Apart from the use of Dexafast to induce parturition in cattle, corticosteroids are not recommended for 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.
Use of the product in lactating cows may cause a reduction in milk yield.
See also section “Adverse Reactions”.

Interaction with other medicinal products and other forms of interaction:
Concurrent use with non-steroidal anti-inflammatory drugs may exacerbate gastrointestinal tract ulceration.

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

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.

Overdose (symptoms, emergency procedures, antidotes):
An overdose can induce drowsiness and lethargy in horses.
See also section “Adverse Reactions”.

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

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION>

Pack sizes:
1 x 20 ml, 6 x 20 ml, 12 x 20 ml
1 x 50 ml, 6 x 50ml, 12 x 50 ml
1 x 100 ml, 6 x 100 ml, 12 x 100 ml

Not all pack sizes may be marketed.

To be supplied only on veterinary prescription.

Approved: 24 December 2018