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 AND OTHER SUBSTANCES

1 ml contains:

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

3. 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

4. TARGET SPECIES

Horses, cattle, pigs, dogs, cats

5. INDICATION(S)

Read the package leaflet before use.

6. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Horses: IV, IM, IA
Cattle, pigs, dogs and cats: IM

7. WITHDRAWAL PERIODS

Withdrawal periods:

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf-life after first opening of the immediate packaging: 28 days

9. SPECIAL STORAGE PRECAUTIONS

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

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 AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria SA
Calle Esmeralda, 19
08950 Esplugues de Llobregat
Spain
(The name of the marketing authorisation holder may be replaced with a logo.)

Distributor
FORTE Healthcare Limited,
Block 3, Unit 9,
CityNorth Business Campus,
Stamullen, Co.
Meath. K32 D990
Republic of Ireland

14. MARKETING AUTHORISATION NUMBERS

Vm 36547/5008

15. BATCH NUMBER

Lot{number}

16. SPECIAL WARNING(S), IF NECESSARY

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V ('To be supplied only on veterinary prescription')

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 ml contains:

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

3. TARGET SPECIES

Horses, cattle, pigs, dogs, cats

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.
Horses: IV, IM, IA
Cattle, pigs, dogs and cats: IM

5. WITHDRAWAL PERIODS

Withdrawal periods:

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. EXPIRY DATE

Exp. {mm/yyyy}

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

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria SA
Calle Esmeralda, 19
08950 Esplugues de Llobregat
Spain
(The name of the marketing authorisation holder may be replaced with a logo.)

9. BATCH NUMBER

Lot {number}

10. PACKAGE SIZE

50 ml,
100 ml

11. INDICATION(S)

Read the package leaflet before use.

12. SPECIAL WARNING(S), IF NECESSARY

13. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

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

POM-V ('To be supplied only on veterinary prescription')

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

Keep out of the sight and reach of children.

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36547/5008

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafast 2 mg/ml solution for injection for horses, cattle, pigs, dogs and cats
(The target species may be replaced with a pictogram.)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

1 ml contains:

Active substance:
Dexamethasone 2.0 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

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

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

20 ml
50 ml

6. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

7. WITHDRAWAL PERIOD

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

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafast 2 mg/ml Solution for Injection for Horses, Cattle, Pigs, Dogs and Cats

2. COMPOSITION

1 ml contains:

Active substance:

Dexamethasone (as dexamethasone sodium phosphate)	2.0 mg

Excipients:

Benzyl alcohol (E1519)	15.6 mg

Clear, colourless solution.

3. TARGET SPECIES

Horses, cattle, pigs, dogs and cats.

4. INDICATIONS FOR USE

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 cases of hypersensitivity to the active substance, to corticosteroids or to any of the excipients.
See also section “Pregnancy and lactation”.

6. SPECIAL WARNING(S)

For Animal Treatment Only

Special precautions for safe use in the target species:
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 or the label to the physician.

This veterinary medicinal product should not be administered by pregnant women.

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 veterinary medicinal product.
Wash hands after use.

Pregnancy and lactation:

Pregnancy:
Apart from the use of Dexafast to induce parturition in cattle, the use of corticosteroids is not recommended for use during pregnancy. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion.

Lactation:
Use of the product in lactating cows may cause a reduction in milk yield.
See also section “Adverse Events”.

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:
An overdose can induce drowsiness and lethargy in horses.
See also section “Adverse Reactions”.

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

7. ADVERSE EVENTS

Horses, cattle, pigs, dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports): hypersensitivity reactions
Undetermined frequency: iatrogenic hyperadrenocorticism (Cushing´s disease)[1], polyuria[2], polydipsia[2], polyphagia[2], sodium retention[3], water retention[3], hypokalaemia[3], cutaneous calcinosis, delayed wound healing, weakened resistance to or exacerbation of existing infections[4], gastrointestinal ulceration[5], hepatomegaly[6], changes in blood biochemical and haematological parameters, hyperglycaemia[7], retained placenta[8], reduced viability of the calf[9] pancreatitis[10], laminitis, milk production decrease

[1] 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.
[2] After systemic administration and particularly during the early stages of therapy.
[3] Upon long-term use.
[4] 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.
[5] May be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma.
[6] Increased serum hepatic enzymes.
[7] Transient.
[8] When used for induction of parturition in cattle, with possible subsequent metritis and/or subfertility.
[9] When used for induction of parturition in cattle particularly at early time points.
[10] Increased risk of acute pancreatitis.

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.
During therapy effective doses suppress the hypothalamo-pituitary-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).

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 using the contact details at the end of this leaflet, or via your national reporting system {national system details}.

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 PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirement

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 36547/5008

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder and contact details to report suspected adverse reactions:
Industrial Veterinaria SA
Calle Esmeralda, 19
08950 Esplugues de Llobregat
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

17. OTHER INFORMATION

Distributor
FORTE Healthcare Limited,
Block 3, Unit 9,
CityNorth Business Campus,
Stamullen, Co.
Meath. K32 D990
Republic of Ireland

Gavin Hall
Approved: 10 November 2025