SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Dexamethasone 2.0 mg
(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 (E1519)	15.6 mg
Sodium chloride	
Sodium citrate dihydrate	
Sodium hydroxide (for pH adjustment)	
Citric acid monohydrate (for pH adjustment)	
Water for injections	

Solution for injection.
Clear, colourless solution.

3. CLINICAL INFORMATION

3.1. Target species

Horses, cattle, pigs, dogs and cats.

3.2. Indications for use for each target species

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.

3.3. 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 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 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.

The 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.

Special precautions for the protection of the environment:
Not applicable.

3.6. 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

3.7. Use during pregnancy, lactation or lay

Pregnancy:
Apart from the use of the product 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 3.6

3.8. 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.

3.9. Administration routes and dosage

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.

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

An overdose can induce drowsiness and lethargy in horses.
See also section 3.6.

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

Not applicable.

3.12. 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

4. PHARMACOLOGICAL INFORMATION

4.1. ATCvet code:

QH02AB02

4.2. Pharmacodynamics

This preparation contains the sodium phosphate ester of dexamethasone, a fluoro-methyl derivative of prednisolone, which is a potent glucocorticoid with minimal mineralocorticoid activity. Dexamethasone has ten to twenty times the antiinflammatory activity of prednisolone.

Corticosteroids suppress the immunologic response by inhibition of dilatation of capillaries, migration and function of leucocytes and phagocytosis. Glucocorticoids have an effect on metabolism by increasing gluconeogenesis.

4.3. Pharmacokinetics

This product contains the sodium phosphate ester of dexamethasone. After extravascular (intramuscular, subcutaneous, intra-articular) administration, this soluble ester of dexamethasone is rapidly resorbed from the injection site followed by immediate hydrolysation into the parent compound, dexamethasone. Absorption of dexamethasone is rapid.
The time to reach maximum plasma concentrations (Cmax) of dexamethasone in cattle, horses, pigs and dogs is within 20 min after intramuscular administration. Bioavailability following i.m. administration (compared to i.v. administration) is high in

all species. Elimination half-life after intravenous administration in horses is 3.5 h. After intramuscular administration, apparent elimination half-life has been shown to range between 1 and 20 hours according to the species.

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: 4 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

Clear glass (Type I Ph. Eur.) vials of 20 ml, 50 ml and 100 ml closed with a bromobutyl rubber stopper and sealed with an aluminium cap.

Carton of 1 x 20 ml, 6 x 20 ml or 12 x 20 ml
Carton of 1 x 50 ml, 6 x 50 ml or 12 x 50 ml
Carton of 1 x 100 ml, 6 x 100 ml or 12 x 100 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. NAME OF THE MARKETING AUTHORISATION HOLDER

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

7. MARKETING AUTHORISATION NUMBER

Vm 43173/3000

8. DATE OF FIRST AUTHORISATION

24 December 2018

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

March 2023

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.

Approved 01 March 2023