

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

### Active substance:

Dexamethasone 2.0 mg  
(as dexamethasone sodium phosphate 2.63 mg)

### 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   |   |
| Citric acid (for pH adjustment)                              |   |
| Sodium hydroxide (for pH adjustment)                         |   |
| Water for injections   |   |

Clear, colourless to slightly brownish aqueous solution.

## 3. CLINICAL INFORMATION

### 3.1 Target species

Horses, cattle, goats, pigs, dogs and cats.

### 3.2 Indications for use for each target species

#### Horses, cattle, goats, pigs, dogs and cats:

Treatment of inflammation and allergic reactions.

#### Horses:

Treatment of arthritis, bursitis or tenosynovitis.

#### Cattle:

Treatment of primary ketosis (acetonemia).

Induction of parturition.

#### Goats:

Treatment of primary ketosis (acetonemia).

### 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 known hypersensitivity to the active substance, to corticosteroids or to any of the excipients.

### 3.4 Special warnings

None.

### 3.5 Special precautions for use

#### Special precautions for safe use in the target species:

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

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 veterinary medicinal product is used in animals with a weakened immune system.

Except in cases of ketosis and induction of parturition, the purpose of corticosteroid administration is to induce 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. Care should be taken not to overdose Channel Island breeds of cattle.

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

This veterinary medicinal product contains dexamethasone which can cause allergic reactions in some people. 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.

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

To avoid the risk from accidental self-injection, pregnant women should not handle this product. Dexamethasone may affect fertility or the unborn child.

This veterinary medicinal product is a skin and eye irritant. Avoid contact with skin and eyes. In the case of accidental contact of the veterinary medicinal product with the skin or eyes, rinse with large amounts of fresh water. If symptoms occur, seek medical advice.

#### Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Horses, cattle, goats, pigs, dogs and cats:

|  |  |
|--|--|
| Very rare<br>(<1 animal / 10,000 animals treated, including isolated reports): | Hypersensitivity reactions.  |
| Undetermined frequency (cannot be estimated from the available data)           | Hyperadrenocorticism (iatrogenic Cushing's disease) <sup>1</sup> ;<br>adrenal gland disorder (atrophy) <sup>2</sup> ;<br>Polyuria <sup>3</sup> ;<br>Polydipsia <sup>3</sup> , polyphagia <sup>3</sup> , delayed wound healing; |

|  |   |
|--|---|
|  | <p>Electrolyte disorder (sodium and water retention, hypokalaemia)<sup>4</sup>, changes in blood biochemical and haematological parameters, hyperglycaemia<sup>5</sup>;</p> <p>Cutaneous calcinosis, skin thinning;</p> <p>Immune system disorder (weakened resistance to infection, exacerbation of existing infections)<sup>6</sup>;</p> <p>Gastrointestinal ulceration<sup>7</sup>, acute pancreatitis<sup>8</sup>;</p> <p>Hepatomegaly<sup>9</sup>;</p> <p>Aggression<sup>10</sup>, depression<sup>11</sup>;</p> <p>Reduced viability of the calf<sup>12</sup>, retained placenta<sup>12,13</sup>;</p> <p>Laminitis;</p> <p>Milk production decrease.</p> |
|--|---|

<sup>1</sup> Involving significant alteration of fat, carbohydrate, protein and mineral metabolism, leading for example to a redistribution of body fat, muscle weakness and wastage, and osteoporosis.

<sup>2</sup> 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 be given to means of minimising problems of adrenal insufficiency following the withdrawal of treatment, e.g. dosing to coincide with the time of the endogenous cortisol peak (i.e. in the morning with regard to dogs and the evening regarding cats) and a gradual reduction of dosage.

<sup>3</sup> particularly during the early stages of therapy.

<sup>4</sup> upon long-term use.

<sup>5</sup> transient.

<sup>6</sup> 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.

<sup>7</sup> may be exacerbated in patients given non-steroidal anti-inflammatory drugs (NSAIDs) and in animals with spinal cord trauma.

<sup>8</sup> increased risk.

<sup>9</sup> associated with increased serum hepatic enzymes.

<sup>10</sup> in dogs.

<sup>11</sup> occasionally in cats and dogs.

<sup>12</sup> when the product is used for induction for parturition in cattle.

<sup>13</sup> with possible subsequent metritis and/or subfertility.

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:

Apart from the use of the veterinary medicinal product to induce parturition in cattle, corticosteroids are 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 corticosteroids in lactating cows and goats may cause a temporary reduction in milk yield. Use in suckling animals only according to the benefit-risk assessment by the responsible veterinarian. See also the section adverse events.

### 3.8 Interaction with other medicinal products and other forms of interaction

Concurrent use with non-steroidal anti-inflammatory drugs (NSAIDs) 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**

Horses: intravenous, intramuscular, intra-articular and periarticular use.

Dogs and cats: intravenous, intramuscular and subcutaneous use.

Cattle, goats and pigs: intravenous and intramuscular use.

#### 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.

| <b>Species</b>              | <b>Dosage</b>  |
|-----------------------------|--|
| Horses, cattle, goats, pigs | 0.06 mg of dexamethasone/kg body weight.<br>(1.5 ml of veterinary medicinal product/50 kg body weight) |
| Dogs, cats                  | 0.1 mg of dexamethasone/ kg body weight.<br>(0.5 ml of veterinary medicinal product/10 kg body weight) |

#### For the treatment of primary ketosis (acetonemia):

A dose of 0.02-0.04 mg of dexamethasone/kg body weight (cattle: 5-10 ml of veterinary medicinal product per 500 kg body weight; goats: 0.65-1.3 ml of veterinary medicinal product per 65 kg body weight) given by single intramuscular injection is advocated dependent on the size of the animal and the duration of the signs. Higher doses (i.e. 0.04 mg/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 of dexamethasone/kg body weight (corresponding to 10 ml of veterinary medicinal product for a cow weighing 500 kg) after day 260 of pregnancy. Parturition will normally occur within 48-72 hours.

#### For the treatment of arthritis, bursitis or tenosynovitis by intra-articular or periarticular injection in the horse:

Dose 1-5 ml of veterinary medicinal product per treatment.

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.

In horses producing food intended for human consumption a total dose of 0.06 mg dexamethasone/kg body weight should not be exceeded. Strict asepsis is essential.

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

An overdose can induce drowsiness and lethargy in horses.

See section adverse events.

**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**

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**3.12 Withdrawal periods**

Cattle and goats:

Meat and offal: 8 days.

Milk: 72 hours.

Pigs:

Meat and offal: 2 days following intramuscular administration.

Meat and offal: 6 days following intravenous administration.

Horses:

Meat and offal: 8 days.

Not authorized for use in horses producing milk for human consumption.

**4. PHARMACOLOGICAL INFORMATION**

**4.1 ATCvet code: QH02AB02.**

**4.2 Pharmacodynamics**

Dexamethasone is a potent synthetic glucocorticoid with low mineralocorticoid activity.

Dexamethasone has ten to twenty times the anti-inflammatory activity of prednisolone at an equivalent molar dose.

Corticosteroids may decrease the immune response. Indeed, they inhibit capillary dilatation, leukocyte migration and phagocytosis. Glucocorticoids have an effect on metabolism by increasing gluconeogenesis. Administration of dexamethasone mimics the effects of cortisol and therefore, produces a signal that initiates the induction of parturition in ruminants if the foetus is alive.

**4.3 Pharmacokinetics**

After administration of the veterinary medicinal product intramuscularly, dexamethasone sodium phosphate is rapidly absorbed and hydrolysed to dexamethasone (base) giving a rapid and short-acting response (approximately 48 hours).  $T_{max}$  in cattle, goats, horses, pigs, dogs and cats is reached within 30 minutes after intramuscular administration.  $T_{1/2}$  (half-life time) varies between 5 and 20 hours depending on the species. The bioavailability after intramuscular administration is approximately 100%.

**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: 3 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**

50 ml and 100 ml clear type I glass vials closed with a coated bromobutyl rubber stopper and aluminium cap in a cardboard box.

Pack sizes:

Cardboard box with 1 vial of 50 ml.

Cardboard box with 1 vial of 100 ml.

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal products 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**

Alfasan Nederland B.V.

## **7. MARKETING AUTHORISATION NUMBER(S)**

VPA10980/019/001

## **8. DATE OF FIRST AUTHORISATION**

28/01/2022

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

18/11/2024

## **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) (<https://medicines.health.europa.eu/veterinary>).

