# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafort Veterinary

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

| | |
|---|---|
| Dexamethasone (as sodium phosphate) | 1mg |
| Dexamethasone (as phenylpropionate) | 2mg |

Excipients:

| | |
|---|---|
| Benzyl alcohol | 10.4 mg |

For the full list of excipients, see section 6.1

## 3. PHARMACEUTICAL FORM

Suspension for injection.
White to off-white suspension.

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Horses, cattle, dogs and cats.

### 4.2 Indications for use, specifying the target species

For the treatment of primary ketosis, various inflammatory conditions like arthritis and other orthopedic conditions, shock, stress, allergic conditions in horses, cattle, dogs and cats.

### 4.3 Contra-indications

Except in emergency situations the product should not be used in animals suffering from diabetes, chronic nephritis, renal disease, congestive heart failure, osteoporosis and in viral infections during the viraemic stage.

Do not use in case of hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

### 4.4 Special warning for each target species

See 4.6 below.

## 4.5 Special precautions for use

(i) Special precautions for use in animals

Shake vial well before use. See 4.3 above and 4.6 below.

(ii) Special precautions to be taken by the person administering the medicinal product to the animals.

Care should be taken to avoid accidental self-injection. If accidental self –injection occurs, seek medical attention and show the label to the doctor. Avoid contact with skin and eyes. In the event of accidental eye or skin contact, wash/irrigate the area with clean running water. Seek medical attention if irritation persists. Wash hands after use.

## 4.6 Adverse reactions (frequency and seriousness)

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.

Steroids themselves, during treatment, may cause Cushingoid symptoms 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, eg dosing to coincide with the time of the endogenous cortisol peak (ie in the morning with regard to dogs and the evening re cats) and a gradual reduction of dosage (for further discussion see standard texts).

Systematically 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).*

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.

In very rare cases, hypersensitivity reactions might occur.

Care should be taken when the product is used for the treatment of laminitis in horses, where there is a possibility that such treatment could worsen the condition. The use of the product in horses for other conditions could induce laminitis and careful observations during the treatment period should be made.

Use of the product in lactating cows may cause a reduction in milk yield.

During a course of treatment the situation should be reviewed frequently by close veterinary supervision.

Systemic corticosteroid therapy is generally contra-indicated in patients with renal disease and diabetes mellitus. Gastro-intestinal 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. Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product.
Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form https://sideeffects.health.gov.il

## 4.7 Use during pregnancy or lactation

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.

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

See 4.6 above.

## 4.9 Amounts to be administered and administration route

Before use shake vial upright thoroughly for 30 seconds.

Dexafort should be administered by intramuscular injection using normal aseptic techniques by use of a min. 21 G cannula. .

Dexafort should be administered by intramuscular injection using normal aseptic techniques.
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 advised 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 | 1 ml/50 kg |
| Dog, cat | 0.5 ml/10 kg |

the treatment of primary ketosis in cattle (acetonaemia)
A dose of 5-10 ml dependent on the size of the cow. Since blood sugar levels rise rapidly following injection of the product, through the action of dexamethasone sodium phosphate and raised levels are maintained for several days, the product is particularly useful in cases that present late and there is seldom a need to repeat the dose.
In the case of cows in poor bodily condition, to avoid prolonged stimulation of gluconeogenesis at the expense of body fat reserves, use a product containing only the quick-acting ester.

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

See 4.6 above.

### 4.11 Withdrawal periods

Cattle: Meat – 63 days
Milk – 7 days

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: glucocorticoid
ATC code: QH02AB02

Dexamethasone is a highly potent corticosteroid. It has minimal mineralocorticosteroid activity and potent glucocorticosteroid activity. Dexamethasone has gluconeogenic, anti-inflammatory, anti-allergenic activity and it induces parturition. Dexafort is a dexamethasone preparation with a rapid onset of activity and a relatively long duration of action. It contains the disodium phosphate ester and phenylpropionate ester of dexamethasone.

### 5.2 Pharmacokinetic particulars

After intramuscular administration, the two dexamethasone esters are resorbed from the injection site followed by immediate hydrolysation into the parent

compound, dexamethasone. Dexamethasone sodium phosphate is resorbed rapidly from the injection site, thus ensuring a rapid onset of activity. Dexamethasone phenylpropionate is resorbed more slowly from the injection site, thus ensuring a prolonged duration of activity.
The time to reach maximum plasma levels of dexamethasone after intramuscular injection in cattle, horse, and dog is within 60 min after injection. Elimination half-lives after intramuscular administration are between 30 and 96 hours depending on the species. This relatively long half-life is caused by the relatively slow resorption of dexamethasone phenylpropionate from the injection site and is a combination of absorption and elimination half life. Bioavailability after intramuscular administration is approximately 100%.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium Citrate
Benzyl Alcohol
Sodium Chloride
Tragacanth
Methylcellulose MH50
Sodium hydroxide 1N
Hydrochloric acid 1N
Water for injections

### 6.2 Incompatibilities

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

### 6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.
Shelf life after first opening the immediate packaging: 28 days.

### 6.4 Special precautions for storage

Store below 25°C.
Keep the container in the outer carton in order to protect from light.
Store in upright position.
Following withdrawal of the first dose, use within 28 days.
Discard unused material.

### 6.5 Nature and composition of immediate packaging

Clear glass (Type I Ph.Eur) vials of 50 ml closed with a halogenated butyl rubber stopper and sealed with an aluminium cap covered with a blue polyethylene disk (Flip-off cap).

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of as toxic waste, do not throw to sewer.

## 7. MANUFACTURER

Vet Pharma Friesoythe GmbH
Sedelsberger strasse 2, 26169 Friesoythe,
Germany.

## 8. LICENSE HOLDER

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## 9. LICENSE NUMBER

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