

## **PARTICULARS TO APPEAR ON THE OUTER PACKAGE – CARDBOARD BOX**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Dexafort Suspension for Injection

### **2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

Dexamethasone phenylpropionate	2.67 mg (equivalent to 2 mg dexamethasone)
Dexamethasone sodium phosphate	1.32 mg (equivalent to 1 mg dexamethasone)

### **3. PACKAGE SIZE**

50 ml

### **4. TARGET SPECIES**

Horses, cattle, dogs and cats.

### **5. INDICATIONS**

### **6. ROUTES OF ADMINISTRATION**

Intramuscular use.

Before use shake vial upright thoroughly for 30 seconds.

### **7. WITHDRAWAL PERIODS**

Withdrawal periods:

Cattle: Meat and offal: 63 days  
Milk: 144 hours

Horses: Not for use in horses intended for human consumption. Treated horses may never be slaughtered for human consumption. The horses must have been declared as not intended for human consumption under national horse passport legislation.

### **8. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days.

### **9. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25 °C.

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

Store in an upright position.

**10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”**

Read the package leaflet before use.

User warning:

Take care to avoid accidental self-injection.

**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 OF THE MARKETING AUTHORISATION HOLDER**

MA Holder:

Intervet International B.V.

Distributor in Northern Ireland:

Intervet Ireland Ltd.

**14. MARKETING AUTHORISATION NUMBERS**

Vm 06376/4086

**15. BATCH NUMBER**

Lot {number}

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE – VIAL LABEL**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Dexafort Suspension for Injection

### **2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains:

Dexamethasone phenylpropionate	2.67 mg (equivalent to 2 mg dexamethasone)
Dexamethasone sodium phosphate	1.32 mg (equivalent to 1 mg dexamethasone)

50 ml

### **3. TARGET SPECIES**

Horses, cattle, dogs and cats.

### **4. ROUTES OF ADMINISTRATION**

Intramuscular use.

Read the package leaflet before use.

### **5. WITHDRAWAL PERIODS**

Withdrawal periods:

Cattle: Meat and offal: 63 days

Milk: 144 hours

Horses: Not for use in horses intended for human consumption (see package leaflet).

### **6. EXPIRY DATE**

Exp. {mm/yyyy}

Once broached use within 28 days.

Once broached use by:

### **7. SPECIAL STORAGE PRECAUTIONS**

Do not store above 25 °C.

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

Store in an upright position.

### **8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Intervet International B.V.

**9. BATCH NUMBER**

Lot {number}

## **PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

### **PACKAGE LEAFLET**

#### **1. Name of the veterinary medicinal product**

Dexafort Suspension for Injection

#### **2. Composition**

Each ml contains:

##### **Active substances:**

Dexamethasone phenylpropionate	2.67 mg (equivalent to 2 mg dexamethasone)
Dexamethasone sodium phosphate	1.32 mg (equivalent to 1 mg dexamethasone)

##### **Excipient:**

Benzyl alcohol	10.4 mg
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White to off-white suspension.

#### **3. Target species**

Horses, cattle, dogs and cats.

#### **4. Indications for use**

The product is indicated for use as an anti-inflammatory and anti-allergic agent in horses, cattle, dogs and cats, and for the treatment of primary ketosis in cattle. The product can also be used to induce parturition in cattle.

#### **5. Contraindications**

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.

#### **6. Special warnings**

##### Special warnings:

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.

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.

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

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-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, 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 for cats) and a gradual reduction of dosage (for further discussion see standard texts).

Corticosteroids may delay wound healing and the immunosuppressive effect can weaken the immune system or worsen pre-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.

Systemic corticosteroid therapy is generally contraindicated in patients with renal disease and diabetes mellitus. 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.

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

The veterinary medicinal product can cause allergic reactions. People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product.

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.

To avoid the risk of self-injection, pregnant women should not handle the veterinary medicinal product.

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.

Pregnancy and lactation:

Apart from the use of the product 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.

Interaction with other medicinal products and other forms of interaction:  
Refer to section “Special precautions for safe use in the target species”.

Overdose:  
Refer to section “Adverse events”.

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, dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Polyuria <sup>1</sup> ; Polydipsia, Polyphagia <sup>1</sup> ; Other blood disorder <sup>2</sup> ; Cutaneous calcinosis; Delayed healing; Hypersensitivity reaction; Hepatomegaly; Elevated liver enzymes.
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<sup>1</sup> Particularly during the early stages of therapy.

<sup>2</sup> Sodium and water retention and hypokalemia when administered long-term.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at: Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>  
e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

## 8. Dosage for each species, routes and method of administration

Intramuscular use.

Use normal aseptic techniques and a minimum of a 21 gauge cannula.  
Before use shake vial upright thoroughly for 30 seconds.

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

For the treatment of primary ketosis in cattle (acetoanaemia): 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.

For the induction of parturition: The product may be used to induce parturition in cattle in the last trimester and before day 260 of pregnancy. Where this is required e.g., in the cases of trauma to the cow or possibly because the date of calving is not known a single dose of 10 ml followed 6-12 days later by an injection of a short acting corticosteroid such as dexamethasone sodium phosphate alone is recommended. In the majority of cases parturition will be induced within 3 days of the second injection.

## **9. Advice on correct administration**

To ensure a correct dosage, body weight should be determined as accurately as possible.

To measure small volumes of less than 1 ml a suitably graduated syringe should be used to ensure accurate administration of the correct dose.

## **10. Withdrawal periods**

Cattle: Meat and offal: 63 days  
Milk: 144 hours

Horses: Not to be used in horses intended for human consumption.  
Treated horses may never be slaughtered for human consumption.  
The horse must have been declared as not intended for human consumption under national horse passport legislation.

## **11. Special storage precautions**

Keep out of the sight and reach of children.

Do not store above 25 °C.  
Keep the container in the outer carton in order to protect from light.  
Store in an upright position.

Shelf life after first opening the immediate packaging: 28 days.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.

## **12. Special precautions for disposal**

Medicines should not be disposed of via wastewater.  
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

applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

### **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

### **14. Marketing authorisation numbers and pack sizes**

Vm 06376/4086

#### Pack size:

Cardboard box containing a 50 ml vial.

### **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](http://www.gov.uk).

### **16. Contact details**

#### Marketing authorisation holder:

Intervet International B.V.  
Wim de Körverstraat 35  
5831 AN Boxmeer  
Netherlands

#### Manufacturer responsible for batch release:

Vet Pharma Friesoythe GmbH  
Sedelsberger Strasse 2-4  
26169 Friesoythe  
Germany

#### Local representative:

MSD Animal Health UK Limited  
Walton Manor, Walton  
Milton Keynes  
MK7 7AJ, United Kingdom

#### Contact details to report suspected adverse reactions:

##### **UK(GB)**

MSD Animal Health UK Ltd.  
Tel.: +44 (0)1908 685685

##### **UK(NI)**

Intervet Ireland Ltd.

Tel.: +353 (0)1 2970220

Distributor in Northern Ireland:  
Intervet Ireland Ltd.  
Magna Drive, Magna Business Park  
Citywest Road, Dublin 24, Ireland

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

#### **17. Other information**

POM-V Veterinary medicinal product subject to prescription.

*Gavin Hall*  
Approved 20 August 2025