PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafort Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Dexamethasone 2.67 mg (as Dexamethasone Phenylpropionate)

Dexamethasone 1.32 mg (as Dexamethasone Sodium Phosphate)

Benzyl Alcohol (E1519) 10.4 mg.

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Horses, cattle, dogs and cats.

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Aqueous suspension for intramuscular injection.

Before use shake vial upright thoroughly for 30 seconds.

Read package leaflet for directions and warnings before use.

Dosage:

Horses, cattle 1 ml/50 kg.

Cats and dogs 0.5 ml/10 kg.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle: Meat - 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.

9. SPECIAL WARNING(S), IF NECESSARY

Take care to avoid accidental self-injection.

Read package leaflet for directions and warnings before use.

10. EXPIRY DATE

Expiry end of:

Following withdrawal of the first dose use the product within 28 days.

Discard unused material.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

Store in upright position.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

FOR ANIMAL TREATMENT ONLY

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

KEEP OUT OF THE SIGHT AND REACH OF CHILDREN.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

Wim de Korverstraat 35

5831 AN

Boxmeer

Netherlands

Distributed in Northern Ireland by:

Intervet Ireland Ltd

Magna Drive,

Magna Business Park

Citywest Road, Dublin 24

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/4086

17. MANUFACTURER’S BATCH NUMBER

BN:

PARTICULARS TO APPEAR ON THE THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafort Suspension for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Dexamethasone sodium phosphate: 1.32 mg.

Dexamethasone phenylpropionate: 2.67 mg.

Benzyl alcohol (E1519) 10.4 mg.

3. PHARMACEUTICAL FORM

Suspension for Injection

4. PACKAGE SIZE

50 ml

5. TARGET SPECIES

Horses, cattle, dogs and cats.

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

I.M.

Read the package leaflet for directions, warnings, storage and disposal advice before use.

8. WITHDRAWAL PERIOD

Withdrawal periods:

Cattle: Meat - 63 days. Milk - 144 hours.

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet for directions, warnings, storage and disposal advice before use.

10. EXPIRY DATE

Expiry end of

Once vial is broached, use within 28 days.

Once broached, use by:_____

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet for directions, warnings, storage and disposal advice before use.

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

Store in upright position.

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

Read the package leaflet for directions, warnings, storage and disposal advice before use.

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

[Distribution category]

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

Wim de Korverstraat 35

5831 AN

Boxmeer

Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06376/4086

17. MANUFACTURER'S BATCH NUMBER

BN:

PACKAGE LEAFLET FOR:

Dexafort Suspension for Injection

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder

Intervet International B.V.

Wim de Korverstraat 35

5831 AN

Boxmeer

Netherlands

Manufacturer for the batch release:

Vet Pharma Friesoythe GmbH,

Sedelsberger Strasse 2,

26169 Friesoythe, Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafort Suspension for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Active substances:

Each ml contains:

Dexamethasone sodium phosphate 1.32 mg

Dexamethasone phenylpropionate 2.67 mg

Excipients:

Benzyl alcohol (E1519) 10.4 mg

4. INDICATION(S)

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.

Use during pregnancy or 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.

6. ADVERSE REACTIONS

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 hypothalamopituitreal-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.

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.

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.

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.

In very rare cases, hypersensitivity reactions might occur.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses, cattle, dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dexafort should be administered by intramuscular injection using normal aseptic techniques.

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 (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.

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

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

10. WITHDRAWAL PERIOD(S)

Cattle: Meat – 63 days.

Milk – 144 hours.

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.

Following withdrawal of the first dose, use within 28 days.

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 container should be determined. This discard date should be written in the space provided.

Discard unused material.

Store in upright position.

12. SPECIAL WARNING(S)

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

The veterinary medicinal product can cause allergic reactions. Persons with known hypersensitivity to the active substance or 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 insert 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. 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.

15. OTHER INFORMATION

For animal treatment only.

Pharmacotherapeutic group: glucocorticoid.

ATC code: QH02AB02

Pharmacodynamic properties

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.

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%.

Pack size

1x 50 ml vial.

Not all pack sizes may be marketed.

MA number

Vm 06376/4086

Legal Category

POM-V
To be supplied only on veterinary prescription.

Distributor in Northern Ireland

Intervet Ireland Ltd.

Magna Drive

Magna Business Park

Citywest Road

Dublin 24

Approved 10 December 2024

Gavin Hall