SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dexafort Veterinary
Suspension for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Dexamethasone (as phenylpropionate) 2 mg
Dexamethasone (as sodium phosphate) 1 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	10.4 mg
Sodium citrate dihydrate	
Sodium chloride	
Tragacanth	
Methylcellulose	
Sodium hydroxide 1N	
Hydrochloric acid 1N	
Water for injection	

White to off-white suspension.

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, dogs and cats.

3.2 Indications for use, for each 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.

3.3 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.

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

3.4 Special warnings

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.

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 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-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, 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses, cattle, dogs and cats:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Polyuria[1]; Polydipsia, Polyphagia[1]; Other blood disorder[2]; Cutaneous calcinosis; Delayed healing; Hypersensitivity reaction; Hepatomegaly; Elevated liver enzymes.

[1] Particularly during the early stages of therapy.
[2] Sodium and water retention and hypokalemia when administered long-term.

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

3.7 Use during pregnancy, lactation or lay

Pregnancy and 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.

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

3.8 Interaction with other medicinal products and other forms of interaction

Refer to section 3.5, “Special precautions for safe use in the target species”.

3.9 Administration routes and dosage

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

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.

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

Refer to 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

Cattle: Meat – 63 days
Milk – 7 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH02AB02

4.2 Pharmacodynamics

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. This veterinary medicinal product 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.

4.3 Pharmacokinetics

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, horses, and dogs is within 60 minutes 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%.

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

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

5.3 Special precautions for storage

Store below 25°C.
Keep the container in the outer carton in order to protect from light.
Store in an upright position.

5.4 Nature and composition of immediate packaging

Clear glass (Type I) 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).

Pack size:
Carton box containing a 50 ml vial.

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.

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. MANUFACTURER

Intervet International B.V. (MSD Animal Health), Boxmeer, Netherlands.

7. LICENSE HOLDER

Intervet Israel Ltd.
Industrial Zone Neve Ne'eman 2,
Hod Hasharon 45240,
Israel

8. LICENSE NUMBER

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