CONSUMER PACKAGE INSERT FOR VETERINARY MEDICINAL PRODUCT

The medicine is dispensed with a veterinarian's prescription only
For animal use only

1. NAME OF THE MEDICINAL PRODUCT:

Dexafort Veterinary
Suspension for injection

2. COMPOSITION:

Each ml contains:
Active substances:
Dexamethasone (as sodium phosphate) 1 mg
Dexamethasone (as phenylpropionate) 2 mg

Preservative:
Benzyl alcohol 10.4 mg

For the full list of excipients, see section 13 – “Additional information”.

3. WHAT IS THE MEDICINAL PRODUCT INTENDED FOR:

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

Therapeutic group: glucocorticoids

4. CONTRAINDICATIONS:

Do not use in case of sensitivity to the active substance or to any of the excipients listed in section 13.

Except in emergency situations the product should not be used in animals suffering from:

•Diabetes
•Chronic nephritis
•Renal disease
•Congestive heart failure
•Osteoporosis
•Viral infections during the viraemic stage

5. SIDE EFFECTS:

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. For example, redistribution of body fat, muscle weakness and wastage and osteoporosis may result. During therapy, effective doses suppress the hypothalamopituitreal-adrenal axis (HPA 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, such as dosing to coincide with the time of the endogenous cortisol peak (that is, in the morning with regard to dogs and the evening for 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.

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 gastro-intestinal ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs (NSAIDs) 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 consumer leaflet, please inform your veterinary surgeon.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects due to Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link:

https://sideeffects.health.gov.il

6. TARGET SPECIES:
Horses, cattle, dogs and cats.

7. METHOD OF ADMINISTRATION AND DOSAGE:
Dexafort Veterinary should be administered by intramuscular injection using normal aseptic techniques.

For the treatment of allergic or inflammatory 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.

8. HOW TO USE THE PRODUCT:
Before use shake vial upright thoroughly for 30 seconds.

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

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

9. WITHDRAWAL PERIOD:

Cattle: meat - 63 days
milk - 7 days

10. WARNINGS:

Special warnings relating to use of the medicine in animals

Shake the vial well before use.
See contraindications and side effects sections.

Special warnings relating to the safety of the person administering the 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 the area with clean running water. Seek medical attention if irritation persists.

Wash hands after use.

Pregnancy and lactation in treated animal

Corticosteroids are not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration at late pregnancy may cause early parturition or abortion.

Interactions with other medicinal products and other types of interactions

See side effects section.

Overdose

See side effects section.

Incompatibility

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

11. STORAGE INSTRUCTIONS:

- Avoid poisoning! This medicinal product and any other medicinal products, should be kept in a safe place, out of the reach and sight of children and/or infants in order to protect from poisoning.

- Do not use the medicinal product after the expiry date (exp. Date) appearing on the package. The expiry date refers to the last day of that month.

- Storage conditions:
  Store below 25°C.
  Keep the vial in the outer carton in order to protect from light.
  Store the product in upright position.
  Discard unused material.

- Shelf life after first opening: 28 days.

- When the vial is opened for the first time, determine the expiry date for the product that remains in the vial, considering the shelf life after first opening indicated in this leaflet. Write on the package the date by which the product has to be discarded.

12. INSTRUCTIONS REGARDING DISPOSAL OF THE MEDICINAL PRODUCT/REMNANTS OF THE MEDICINAL PRODUCT AFTER USE:

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.

13. ADDITIONAL INFORMATION:

- In addition to the active substance, the medicine also contains:
  Sodium citrate, Benzyl alcohol, Sodium chloride, Tragacanth, Methylcellulose, Sodium hydroxide 1N, Hydrochloric acid 1N, Water for injection.

- What the medicine looks like and the content of the package:
  A white to off-white suspension.
  The package: A glass vial of 50 ml, closed with a rubber stopper (butyl) and aluminum overseal, with a blue flip-off cap.

- **Pharmacodynamic properties**
  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 also induces parturition. Dexafort Veterinary is a dexamethasone preparation with a rapid onset of activity and a relatively long duration of action. It contains the disodium phosphate ester of dexamethasone and phenylpropionate ester of dexamethasone.

- **Pharmacokinetic properties**
  After intramuscular administration, the two dexamethasone esters are absorbed

from the injection site, followed by immediate hydrolyzation, yielding the parent compound, dexamethasone. Dexamethasone sodium phosphate is absorbed rapidly from the injection site, thus ensuring a rapid onset of activity. Dexamethasone phenylpropionate is absorbed 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. Half-lives after intramuscular administration range between 30 and 96 hours, depending on the type of animal. This relatively long half-life is caused by the relatively slow absorption of dexamethasone phenylpropionate from the injection site and is a combination of elimination and absorption half-life. Bioavailability after intramuscular administration is approximately 100%.

- Manufacturer name and address:
  Vet Pharma Friesoythe GmbH, Sedelsberger Strasse 2, 26169 Friesoythe, Germany.
- Registration holder and address: Intervet Israel Ltd., Industrial Park Neve Ne'eman, Hod Hasharon 45240.

Revised in January 2023 according to MOHs guidelines.

Registration number of the medicinal product in the National Drug Registry of the Ministry of Health: 082-08-91518-00