1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Depo-Medrone V 40 mg/ml suspension for injection for dogs, cats and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
Methylprednisolone acetate 40.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Myristyl-gamma-picolinium chloride	0.2 mg
Polyethylene Glycol 3350	
Sodium Chloride	
Sodium Hydroxide (for pH adjustment)	
Hydrochloric Acid (for pH adjustment)	
Water for injections	

White aqueous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Dogs, cats and horses.

3.2 Indications for use for each target species

For the treatment of, or as part of a therapeutic regime for, inflammatory and allergic conditions in dogs and cats such as allergic or non-specific inflammatory dermal conditions, musculoskeletal conditions, ocular/otic inflammatory conditions and other inflammatory/allergic conditions that are likely to respond to corticosteroid therapy e.g. autoimmune disorders. For the treatment of, or as part of a therapeutic regime for, musculo-skeletal conditions in horses.

3.3 Contraindications

Not to be given intravenously.
The technique of aspiration should be employed, as appropriate, to avoid intravascular administration.

Intra-synovial, intra-tendinous or other injections of corticosteroids for local effect are contra-indicated in the presence of acute infectious conditions.

Systemic corticosteroid therapy is generally contra-indicated in patients with arrested tuberculosis, peptic ulcer, renal disease, diabetes mellitus and Cushing's syndrome.
The veterinary medicinal product is contraindicated for the treatment of laminitis in horses.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

It is important that treatment of working or racing animals is followed by a period of rest to allow resolution of the clinical condition.
Aseptic injection techniques should be practised. Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, the product should be discarded.

Exacerbation of pain, further loss of joint motion, with fever and malaise following intra-synovial injection may indicate that the condition has become septic and appropriate therapy should be instituted immediately. Animals receiving corticosteroids should be monitored for signs of infection and, where necessary, appropriate antimicrobial therapy instigated.

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It is recommended that, where joint therapy is indicated, a radiological examination is undertaken prior to treatment to evaluate the presence of fractures. If fractures are present, corticosteroid therapy should only be used with utmost caution if permanent damage is to be avoided.

Anti-inflammatory corticosteroids, such as methylprednisolone, 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. The continued or prolonged use of this product is not generally recommended.

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, signs 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. a gradual reduction of dosage (for further discussion see standard texts).

Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections. In the presence of bacterial infection, anti-bacterial 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.

During a course of treatment, the clinical condition of the animal should be reviewed regularly by close veterinary supervision.

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

Care must be taken to avoid self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.
Accidental spillage on the skin should be washed off immediately with soap and water.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Dogs, cats and horses:

Very common (>1 animal / 10 animals treated):	Polyuria[1] Polydipsia[1], Polyphagia[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastric ulcer[2], Small intestine ulcer[2], Pancreatitis Adrenal gland disorder[3] Hepatomegaly Other immune system disorder[4] Elevated liver enzymes, Hypokalaemia[6], Hypernatremia[6] Laminitis, Muscle wasting, Muscle weakness, Osteoporosis Cutaneous calcinosis, Skin thinning[7] Delayed healing[5], Oedema[6]

[1] When administered systemic, during the early stages of therapy.
[2] May be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in corticosteroid treated animals with spinal cord trauma.
[3] Following cessation of treatment, signs 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. a gradual reduction of dosage.
[4] Corticosteroids may delay wound healing and the immunosuppressant actions may weaken resistance to or exacerbate existing infections.
[5] Delayed wound healing. [6]Long term use.
[6] When applied locally.

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Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Do not use during pregnancy.

There are risks associated with the use, especially systemically, of corticosteroids during pregnancy.

The safety of the veterinary medicinal product has not been established during pregnancy.

Systemic activity of corticosteroids in early pregnancy is known to have caused foetal abnormalities in laboratory animals and in late pregnancy may cause early parturition or abortion.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration of barbiturates, phenylbutazone, phenytoin or rifampicin may enhance the metabolism and reduce the effects of corticosteroids. Response to anticoagulants may also be reduced by corticosteroids.

3.9 Administration routes and dosage

Shake well before use.

The dosage needed may vary according to individual clinical circumstances such as the severity of the condition to be treated, size of animal, and clinical response.

The following dosage recommendations are therefore initial guidelines and may need slight alteration in the light of individual response. An insulin type syringe should be used to measure and administer volumes of less than 1 ml.

Local: Aseptic precautions are important.

Horses: The average initial dose for a large synovial space is 120 mg (3 ml). Smaller spaces will require a correspondingly lesser dose. The intratendinous dose ranges from 80-400 mg (2-10 ml) depending on the size of the tendon.

Dogs: The average initial dose for a large synovial space is 20 mg (0.5 ml). Smaller spaces will require a correspondingly lesser dosage.

Procedure for intra-synovial injection: the anatomy of the area to be injected should be reviewed in order to ensure that the product is properly placed, and that large blood vessels and nerves are avoided. The injection site is located where the synovial cavity is most superficial. The area is prepared for aseptic injection by shaving and disinfection. If there is an excess of synovia and more than 1 ml of the product is to be injected, it is advisable to aspirate a volume of fluid comparable to that which is to be injected. With the needle in place, the aspirating syringe is removed and replaced by a second syringe containing the proper amount of the product to be injected. In some animals, a transient pain or synovial flare may be elicited immediately upon injection and may last for up to two to three days. After injection, the structure may be moved gently a few times to aid mixing of the synovial fluid and the product. The site may be covered with a small sterile dressing.

Following injection, relief from clinical signs may be experienced within 12-24 hours and be sustained for a variable period but averages three to four weeks, with a range of one to more than five weeks. The continued or prolonged use of the product is discouraged.

Intramuscular use:

Horses: The usual intramuscular dose for horses is 200 mg (5 ml).

Dogs and cats: The usual intramuscular dose for dogs and cats is 1-2 mg/kg.

Injections may be repeated in accordance with the severity of the condition and clinical response. Relief from clinical signs is usually sustained for up to three weeks but may range from one to more than four weeks.

For maintenance therapy in chronic conditions, initial doses should be gradually reduced until the smallest effective dose is established.

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

There should be no significant adverse effects from a single accidental overdose.

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

Horses: Not to be used in horses intended for human consumption.

The horse must have been declared as not intended for human consumption under national passport legislation.

4. PHARMACOLOGICALINFORMATION

4.1 ATCvet code: QH02AB04

4.2 Pharmacodynamics

Methylprednisolone is a synthetic glucocorticoid
(1-dihydro-6-alpha-methylhydrocortisone) of which the pharmacological effects are similar to those of hydrocortisone (cortisol). The methylation of the 6^{th} carbon atom in the four-ring structure increases the anti-inflammatory potency by five times as compared to hydrocortisone, but practically eliminates mineralocorticoid activity.

4.3 Pharmacokinetics

Due to these properties, methylprednisolone can be used as a corticosteroid in the treatment of many inflammatory conditions. The acetate salt is a moderately soluble form of methylprednisolone. It is intended for intramuscular or intra-articular (and intra-lesional) use. It has a slow onset of action and a prolonged activity due to its moderate solubility. When injected intramuscularly in horses and dogs, the acetate analogue is hydrolysed to release methylprednisolone, which diffuses into the circulation where it reaches a peak after 24 hours in horses and after 2 to 10 hrs in dogs. The plasma concentration then declines to undetectable levels over 6 days in horses and over 8-10 days in dogs, however pharmacodynamic effects last longer. In both species, methylprednisolone is metabolised in the liver and excreted via urine and faeces as the unchanged substance and its metabolites.

When injected intrasynovially in horses, methylprednisolone acetate is also hydrolysed to methylprednisolone and remains *in situ* for an extended period of time. Only trace amounts are detected in the plasma shortly after intrasynovial injection; this indicates that an adequate local anti-inflammatory activity and a minimal suppression of the HPA axis is to be expected after intra-lesional administration.

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

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25 °C.
Do not freeze.

5.4 Nature and composition of immediate packaging

5 ml Type I glass vial with butyl rubber bung and aluminium overseal containing a white sterile aqueous suspension for injection.

Cardboard box containing 1 x 5 ml vial.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.

7. MARKETING AUTHORISATION NUMBER

VPA10387/021/001

8. DATE OF FIRST AUTHORISATION

06/01/2014

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

01/09/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).