

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Depo-Medrone V 40 mg/ml Suspension for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance

Methylprednisolone acetate 40.0 mg

Excipients

Myristyl-gamma-picolinium chloride 0.2 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Suspension for injection. White aqueous suspension

4 CLINICAL PARTICULARS

4.1 Target Species

Dog, cat and horse

4.2 Indications for use, specifying the target species

Injectable corticosteroid in dogs, cats and horses.

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.

4.3 Contraindications

1. Not to be given intravenously. The technique of aspiration should be employed, as appropriate, to avoid intravascular administration. Intrasynovial, intratendinous or other injections of corticosteroids for local effect are contra-indicated in the presence of acute infectious conditions.

2. Do not mix with any other product for injection at the same site.
3. Systemic corticosteroid therapy is generally contra-indicated in patients with arrested tuberculosis, peptic ulcer, renal disease, diabetes mellitus and Cushing's syndrome.
4. The product is contraindicated for the treatment of laminitis in horses.
5. Do not administer to pregnant animals.

4.4 Special warnings for each 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.

4.5 Special precautions for use

Special precautions for use in animals

Shake container well before use.

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.

It is recommended that Depo-Medrone V is not mixed with any other product for injection at the same site.

Exacerbation of pain, further loss of joint motion, with fever and malaise following intrasynovial 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.

As with any corticosteroid, treatment of working or racing animals should be followed by a period of rest to allow resolution of the clinical condition.

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

Wear protective gloves when using this product. Care must be taken to avoid self-injection.

4.6 Adverse reactions (frequency and seriousness)

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 the 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 adrenocortisol 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).

Systemically 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. Locally applied steroids may cause thinning of the skin and 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, 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.

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 corticosteroid treated animals with spinal cord trauma. Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

The use of corticosteroids in horses may induce laminitis, therefore, during a course of treatment, the clinical condition of the animal should be reviewed regularly by close veterinary supervision.

4.7 Use during pregnancy, lactation or lay

There are risks associated with the use, especially systemically, of corticosteroids 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. The safety of methylprednisolone in canine, feline and equine pregnancy has not been established and is therefore contra-indicated.

4.8 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.

4.9 Amounts to be administered and administration route

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 intrasynovial 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:

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Dogs and cats: Not applicable.

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

Treated animals may never be slaughtered for human consumption.

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet code: QH02AB04

Pharmacotherapeutic group: Corticosteroids for systemic use; Glucocorticoids; Methylprednisolone

5.1 Pharmacodynamic properties

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

5.2 Pharmacokinetic properties

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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Myristyl-Gamma-Picolinium Chloride
Polyethylene Glycol 3350

Sodium Chloride
Sodium Hydroxide (for pH adjustment)
Hydrochloric Acid (for pH adjustment)
Water for Injections

6.2 Incompatibilities

None known.

6.3 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.

6.4 Special precautions for storage

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

6.5 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.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/021/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

July 2017