PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Depo-Medrone™ V 40 mg/ml suspension for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 40 mg methylprednisolone acetate and 0.2 mg myristyl-gamma-picolinium chloride as preservative.

3. PHARMACEUTICAL FORM

Suspension for injection

4. PACKAGE SIZE

5 ml vial

5. TARGET SPECIES

Dogs, cats and horses

6. INDICATIONS

Injectable corticosteroid for intramuscular, intrasynovial or intratendinous administration in dogs, cats and horses. See package leaflet for full indications and dosage instructions.

7. METHOD AND ROUTES OF ADMINISTRATION

Intramuscular, intrasynovial or intratendinous administration

8. WITHDRAWAL PERIOD

Treated horses may never be slaughtered for human consumption. See package leaflet for full details.

9. SPECIAL WARNINGS, IF NECESSARY

Corticosteroids can have a wide range of side effects. See package leaflet for full details.
Discard date:

Operator warnings:

Wear protective gloves when using this product. Accidental spillage onto the skin should be washed off immediately with soap and water. Care must be taken to avoid accidental self-injection.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Do not freeze. Shake well before use.

Keep the vial in this carton.

Shelf-life after first opening the immediate packaging: 28 days.

Discard date:

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

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

POM-V

For animal treatment only.

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

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/5161

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Depo-Medrone™ V 40 mg/ml Suspension for Injection

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each ml contains: 40 mg Methylprednisolone Acetate, plus 0.2 mg myristyl-gamma-picolinium chloride as antimicrobial preservative.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

5 ml

4. ROUTE OF ADMINISTRATION

Corticosteroid.

See package leaflet for full details.

5. WITHDRAWAL PERIOD

-

6. BATCH NUMBER

Batch No.:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Keep out of reach and sight of children.

Do not store above 25°C. Do not freeze. Shake vial before use. 28 day in-use shelf life.

UK: POM-V

Vm 42058/5161

PACKAGE LEAFLET FOR:

Depo-Medrone™ V 40 mg/ml suspension for injection

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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufactured by:
Pfizer Manufacturing Belgium NV
Rijksweg 12
Puurs-Sint-Amands
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Depo-Medrone™ V 40 mg/ml Suspension for Injection

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains Methylprednisolone Acetate 40 mg, plus 0.2 mg myristyl-gamma-picolinium chloride as antimicrobial preservative.

4. INDICATIONS

Injectable corticosteroid.

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, musculo-skeletal 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 which are not intended for human consumption.

5. CONTRAINDICATIONS

Aseptic injection techniques should be practised. Depo-Medrone V must not be given intravenously. The technique of aspiration should be employed, as appropriate, to avoid intravascular injection. Due to the potential for local cosmetic effects, the sub-cutaneous use of this product in show animals is not recommended. Intrasynovial,

intratendinous or other injections of corticosteroids for local effect are contra-indicated in the presence of acute infectious conditions.

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 antibacterial 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 radiologic 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.

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

Systemic corticosteroid therapy is generally contra-indicated in patients with renal diseases and diabetis mellitus. Gastrointestinal 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 corticosteroid treated animals with spinal cord trauma.

The product is contra-indicated for the treatment of laminitis in horses.

Additionally it should be noted that use of the product in horses for other conditions could induce laminitis and careful observations during the treatment period should be made.

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

6. ADVERSE REACTIONS

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 adrenocorticol 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.

Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

7. TARGET SPECIES

Dogs, cats, horses.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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 dosage for a large synovial space is 20 mg (0.5 ml). Smaller spaces will require a correspondingly lesser dosage.

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.

9. ADVICE ON CORRECT ADMINISTRATION

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 signsmay 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.

It is important that treatment of working or racing animals is followed by a period of rest to allow resolution of the clinical condition.

10. WITHDRAWAL PERIODS

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

Do not store above 25°C. Do not freeze. Shake vial before use. Shelf-life after first opening the immediate packaging: 28 days. Discard unused material.

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 discarded should beworked out. This discard date should be written in the space provided on the outer label.

Do not use after the expiry date stated on the label and carton.

12. SPECIAL WARNINGS

For animal treatment only

User Warnings

Wear protective gloves when using this product. Accidental spillage on the skin should be washed off immediately with soap and water.

Care must be taken to avoid self-injection.

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

Unused product, waste material and empty containers should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations. In the UK, guidance may be obtained from your local waste regulation authority.

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

Keep out of reach and sight of children.

Methylprednisolone has achieved a clinically acceptable split between glucocorticoid activity and undesired mineralocorticoid activity. Weight for weight, methyl-prednisolone has five times the anti-inflammatory activity of hydrocortisone and at least 25% greater anti-inflammatory activity than prednisolone but, unlike the latter two

corticosteroids, has virtually no mineralocorticoid activity; therefore the risk of mineralocorticoid induced side effects is relatively low.

Supplied in multidose 5 ml vials.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/5161

Gavin Hall

Approved 14 November 2024