PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARDBOARD BOX}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Depo-Medrone V 40 mg/ml suspension for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Methylprednisolone acetate 40 mg.

3. PACKAGE SIZE

5 ml

4. TARGET SPECIES

Dogs, cats and horses.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular, intrasynovial or intratendinous use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse passport must have been declared as not intended for human consumption under national horse passport legislation.

8. EXPIRY DATE

Exp. {mm/yyy}

Once opened use within 28 days.

Discard date:

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Do not freeze.
Keep the vial in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5161

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {VIAL LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Depo-Medrone V

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Methylprednisolone acetate 40 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 28 days.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:
Methylprednisolone acetate 40.0 mg

Excipients:
Myristyl-gamma-picolinium chloride 0.2 mg

White aqueous suspension.

3. Target species

Dogs, cats and horses.

4. Indications for use

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, musculoskeletal conditions in horses which are not intended for human consumption.

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

6. Special warnings

Special warnings:
None.

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. Due to the potential for local cosmetic effects, the sub-cutaneous use of this product in show animals is not recommended. 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 antibacterial therapy should be instituted immediately. Animals receiving corticosteroids should be monitored for signs of infection and, where necessary, appropriate antimicrobial therapy instigated.

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.

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.

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.

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.

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.

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

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Dogs, cats and horses:

Very common (>1 animal / 10 animals treated):	Polyuria (increased urination)[1] Polydipsia (increased thirst)[1], Polyphagia (increased appetite)[1]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastric ulcer[2], Small intestine ulcer[2], Pancreatitis (inflammation of the pancreas) Adrenal gland disorder[3] Hepatomegaly (enlarged liver) Other immune system disorder[4] Elevated liver enzymes, Hypokalaemia (low blood potassium)[6], Hypernatremia[6] Laminitis, Muscle wasting, Muscle weakness, Osteoporosis Cutaneous calcinosis (calcium deposit in the skin), Skin thinning[7] Delayed healing[5], Oedema (swelling)[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.
[7] When applied locally.

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.
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

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 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.

9. Advice on correct administration

Shake well before use.

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.

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

Keep out of the sight and reach of children.

Do not store above 25 °C.
Do not freeze.
Keep the vial in the outer carton.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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

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

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5161

Cardboard box containing 1 x 5 ml vial.

15. 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.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
United Kingdom
Tel: +44 (0) 345 300 8034

Manufacturer responsible for batch release:
Pfizer Manufacturing Belgium NV
Rijksweg 12
2870 Puurs-Sint-Amands
Belgium

17. Other information

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.

POM-V

Gavin Hall
Approved: 29 October 2026