# PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Powder label}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solu-Medrone V 62.5 mg/ml Powder and Solvent for Solution for Injection

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

125 mg Methylprednisolone
500 mg Methylprednisolone

## 3. PHARMACEUTICAL FORM

Powder and Solvent for Solution for Injection

## 4. PACKAGE SIZE

2 ml (when reconstituted)
8 ml (when reconstituted)

## 5. TARGET SPECIES

Dogs and cats

## 6. INDICATION(S)

Glucocorticoid. For intramuscular or intravenous use in dogs and cats.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramuscular or intravenous use

## 8. WITHDRAWAL PERIOD

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## 9. SPECIAL WARNING(S), IF NECESSARY

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## 10. EXPIRY DATE

Expires end:

## 11. SPECIAL STORAGE CONDITIONS

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

## 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

To be supplied only on veterinary prescription.

For animal treatment only.

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

Keep out of the sight and reach 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 42058/4131

## 17. MANUFACTURER'S BATCH NUMBER

Batch No.:

# PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Folding carton}

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solu-Medrone V 62.5 mg/ml Powder and Solvent for Solution for Injection

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

125 mg Methylprednisolone (as the sodium succinate ester)
500 mg Methylprednisolone (as the sodium succinate ester)

## 3. PHARMACEUTICAL FORM

Powder and Solvent for Solution for Injection

Sterile freeze dried powder with vial of Water for Injection as solvent.

## 4. PACKAGE SIZE

2 ml (when reconstituted)
8 ml (when reconstituted)

## 5. TARGET SPECIES

Dogs and cats

## 6. INDICATION(S)

For intramuscular or intravenous use in dogs and cats, as a glucocorticoid where a pharmacologically active, massive dose is required e.g. shock.

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

See package leaflet for full information on uses and dosage.

## 8. WITHDRAWAL PERIOD

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## 9. SPECIAL WARNING(S), IF NECESSARY

**Contra-indications, warnings etc.:**
See package leaflet for full instructions.

Care should be taken to avoid accidental self-injection of this potent drug.

In the event of contact with eyes, flush with water or isotonic saline for 5-10 minutes.
In the event of contact with skin, wash with soap and water.

## 10. EXPIRY DATE

Expires end:

## 11. SPECIAL STORAGE CONDITIONS

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

Make up immediately before use. Any remaining reconstituted product should be discarded.

Do not mix with calcium solutions.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

POM-V

To be supplied only on veterinary prescription

For animal treatment only.

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

Keep out of the sight and reach 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 42058/4131

## 17. MANUFACTURER'S BATCH NUMBER

Batch No.:

# PARTICULARS TO APPEAR ON THE IMMEDIATE DILUENT LABEL

## 1. NAME OF THE DILUENT

Water for Injection

Solvent for parenteral use

Sterile solvent for reconstituting Solu-Medrone™ V 125 mg

Sterile solvent for reconstituting Solu-Medrone™ V 500 mg

## 2. CONTENT BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

2 ml

7.8 ml

## 3. ROUTES OF ADMINISTRATION

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## 4. STORAGE CONDITIONS

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

## 5. BATCH NUMBER

Batch No.:

## 6. EXPIRY DATE

Expires end:

## 7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Keep out of the sight and reach of children.

Discard any remaining contents after use.

**PACKAGE LEAFLET FOR:** Solu-Medrone™ V 62.5 mg/ml Powder and Solvent for Solution for Injection

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

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

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

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Solu-Medrone V 62.5 mg/ml Powder and Solvent for Solution for Injection

## 3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Vials of 125mg or 500mg methylprednisolone (as the sodium succinate ester) accompanied by vials of 2ml or 7.8ml Water for Injection as solvent for parental use.

## 4. INDICATION(S)

Corticosteroid. For administration to dogs and cats, as a glucocorticoid where a pharmacologically active, massive dose is required with rapid onset of activity; for example, in the treatment of overwhelming infections/toxicity, shock (as evidenced by collapse of peripheral circulation with clinical signs of pallor, weak and rapid pulse, shallow respiration) and spinal cord compression.

The use of relatively massive doses of Solu-Medrone V in cases of shock is well-established. The mechanism of action is believed to be twofold, being firstly a sustained rise in cardiac output with a concomitant decrease in peripheral vascular resistance and secondly the stabilisation of cellular and lysosomal membranes against endotoxic damage.

In the treatment of spinal cord compression, for instance as a consequence of an intervertebral disc rupture/protrusion or a road traffic accident, the mechanism of action of Solu-Medrone V is believed to include at least three mechanisms:

1. a facilitation of neuronal excitability and impulse conduction,

2. an improved spinal cord blood flow and

3. the preservation of spinal cord ultrastructure through a reduction of injury-induced free radical-catalysed lipid peroxidation.

Following the use of Solu-Medrone V at high dosage, there is no need for gradual tailing off, i.e. Solu-Medrone V therapy can be stopped as soon as clinical examination demonstrates a stable and improving patient state.

## 5. CONTRAINDICATIONS

There are risks associated with the use, especially systemically, of corticosteroids during pregnancy. The safety of Solu-Medrone V in canine or feline pregnancy has not been established.

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. Solu-Medrone V is indicated in life threatening conditions where it may be considered that, in pregnant animals, the clinical benefit may outweigh any possible risk.

Except in cases of life threatening conditions, Solu-Medrone V is contra-indicated in cases where the patient is known or suspected to be suffering from viral infection, Cushing’s Syndrome, congestive heart failure, diabetes or severe chronic nephritis.

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

## 6. ADVERSE REACTIONS

Vomiting may occur as a side effect of rapid intravenous treatment. Transient polydipsia, polyuria and hyperaesthesia are also possible side effects. A drop in systemic blood pressure may be produced by a high dose of methylprednisolone sodium succinate.

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

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.

## 7. TARGET SPECIES

Dogs and cats.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For intramuscular or intravenous use in dogs and cats.

Reconstitute aseptically by adding the contents of the solvent provided to the freeze-dried powder. Shake well to ensure the contents are fully dissolved before use.

Reconstituted solution should be used immediately.

Intramuscular or intravenous. Where onset of activity is required within 30-180 minutes the intravenous route should be used; the required dose should be injected slowly over several minutes or given by intravenous infusion. For intravenous infusion the initially prepared solution may be diluted with 5% dextrose in water, isotonic saline solution or 5% dextrose in isotonic saline.

Do not mix with calcium solutions. When treating overwhelming infections/toxicity or shock the dose should be 20 to 30mg methylprednisolone/kg bodyweight (0.32-0.48 ml product/kg); this may be repeated at 4-6 hours for 24-48 hours.

When treating spinal cord compression, the dose should be 30 mg methylprednisolone/kg bodyweight (0.48 ml product/kg) and should be given within the first two hours of trauma for maximum clinical benefit.

The need for conjunctive surgery or other medicinal treatment should be considered according to individual clinical status.

## 9. ADVICE ON CORRECT ADMINISTRATION

During a course of treatment, the situation should be reviewed frequently by close veterinary supervision.

## 10. WITHDRAWAL PERIOD(S)

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## 11. SPECIAL STORAGE PRECAUTIONS

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

Make up immediately before use. Any remaining reconstituted product should be discarded. Do not mix with calcium solutions.

## 12. SPECIAL WARNING(S)

### Operator Warning

In the event of contact with the eyes flush with water or isotonic saline for 5-10minutes. In the event of contact with skin wash with soap and water.

Care should be taken to avoid self-injection of this potent drug.

For animal treatment only.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2023

## 15. OTHER INFORMATION

Pack of single 125mg or 500 mg vial, supplied with a vial of Water for Injection as solvent. Not all pack sizes may be marketed.

POM-V

To be supplied only on veterinary prescription.

Vm 42058/4131

Approved 07 November 2023