SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SOLU-MEDRONE™ V 62.5 mg/ml
Powder and Solvent for Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each vial contains methylprednisolone (as the sodium succinate salt) 125 mg or 500 mg. Each ml of reconstituted solution contains 62.5 mg/ml methylprednisolone.

Diluent:

Water for Injection 2 ml or 7.8 ml

For a full list of excipients see section 6.1

3. PHARMACEUTICAL FORM

Powder and solvent for solution for injection.

4. CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for Use, Specifying the Target Species

Corticosteroid: For administration to dogs and cats, as a glucocorticoid where a pharmacologically active massive dose is required with a 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.

4.3 Contraindications

Except in cases of life threatening conditions, use 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.

4.4 Special warnings for each target species

Not applicable.

4.5 Special precautions for use

Special precautions for use in animals

Aseptic injection techniques should be practised.

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

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

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.

4.6 Adverse reactions (frequency and seriousness)

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 (g.i.t.) 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.

4.7 Use during pregnancy, lactation or lay

There are risks associated with the use, especially systemically, of corticosteroids during pregnancy. The safety of the product 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. The product is indicated in life threatening conditions, where it may be considered that, in pregnant

animals, the clinical benefit may outweigh any possible risk.

4.8 Interaction with other medicinal products and other forms of interaction

Concurrent administration or 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.

4.9 Amounts to be administered and administration route

Reconstitution: 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 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.

When treating overwhelming infections/toxicity or shock, the dose should be 20 to 30 mg methylprednisolone/kg bodyweight (0.32-0.48 ml/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 /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.

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

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

Not applicable.

4.11 Withdrawal Period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Methylprednisolone sodium succinate is a highly water soluble ester of the synthetic glucocorticoid methylprednisolone. It is identical in structure to prednisolone with the exception of the addition of a methyl group at the sixth carbon atom. This enhances the glucocorticoid activity by fivefold versus endogenous cortisol but practically eliminates mineralocorticoid activity.

The formulation is designed for either intramuscular or intravenous administration where a pharmacologically active massive dose is required with a rapid onset of activity.

The use of relatively massive doses 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 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium acid phosphate anhydrous
Sodium phosphate dihydrate

6.2 Incompatibilities

Do not mix with calcium solutions.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 5 years.

Shelf-life after reconstitution according to directions: Use immediately. Any remaining reconstituted product should be discarded.

6.4 Special Precautions for Storage

Do not store above 25°C. Do not freeze. Reconstituted solution should be used immediately.

6.5 Nature and composition of immediate packaging

Glass vial containing 125 mg or 500 mg sterile freeze dried powder together with a vial of water for injection as solvent. Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4131

9. DATE OF THE FIRST AUTHORISATION

24 May 1984

10. DATE OF REVISION OF THE TEXT

August 2020

Approved: 27 August 2020