

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MEDRONE™ V TABLETS 2mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains 2 mg of methylprednisolone, 0.0007 mg of amaranth (E123) and 0.0042 mg of erythrosine (E127). For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Tablet: Oval, scored pink coloured uncoated tablet.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use, specifying the target species

For the treatment of, or as part of a therapeutic regime for inflammatory and allergic conditions 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. immune-mediated disorders.

4.3 Contraindications

Systemic corticosteroid therapy is generally contra-indicated in patients with renal disease and diabetes mellitus.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

(i) Special precautions for use in animals

See under 4.6.

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

Wash hands after use. In the event of accidental ingestion, seek medical advice and show the doctor what has been taken. Veterinary practitioners should use child resistant closures when dispensing this product.

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 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.

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. dosing to coincide with the time of the endogenous cortisol peak (i.e. in the morning with regard to dogs and the evening with regard to cats) and 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 longer term use.

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 g.i.t. ulceration may be exacerbated by steroids in patients given non-steroidal anti-inflammatory drugs and in animals with spinal cord trauma. Steroids may cause enlargement of the liver (hepatomegaly) with increased serum hepatic enzymes.

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

4.7 Use during pregnancy, lactation or lay

Corticosteroids are not recommended for use in pregnant animals. Administration in early pregnancy is known to have caused foetal abnormalities in laboratory animals. Administration in late pregnancy may cause early parturition or abortion.

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 effect 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 severity of the condition to be treated, the anticipated duration of therapy and even to take into account the individuals case history. The following dosage recommendations are therefore initial guidelines and may require modification in the light of individual clinical circumstances.

Bodyweight	Average total daily dosage
1-5 kg	1 mg
5-9 kg	2 mg
9-18 kg	2 to 4 mg
18-36 kg	4 to 8 mg

The initial daily dose should be given in two equally divided doses. In order to control clinical signs of certain autoimmune disorders e.g. *Pemphigus vulgaris*, the initial dosage may have to be higher than that suggested above.

As soon as a satisfactory clinical response is achieved, the daily dose should be reduced gradually, either to termination of treatment in the case of acute conditions or to the minimal effective maintenance dose level in the case of chronic conditions.

The veterinary surgeon may, at his/her discretion, use alternate day therapy in order to maintain minimal effective therapy of chronic conditions: dogs should be treated on every alternate morning and cats on every alternate evening.

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

Significant adverse effects are unlikely following a single accidental overdose. See under 4.6.

4.11 Withdrawal period(s)

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Methylprednisolone is a synthetic glucocorticoid (1-dihydro-6-alpha-methylhydrocortisone). Its 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose Monohydrate
Sucrose
Maize Starch
Calcium Stearate
Maize Starch (dried)
New Rose certified

Colour mixture-
Amaranth (E123)
Erythrocin Sodium (E127)
Sucrose
Maize Starch

6.2 Incompatibilities

None known.

6.3 Shelf life of veterinary medicinal product as packaged for sale

5 years.

6.4 Special precautions for storage

Do not store above 25°C. Store in tightly closed original container. Protect from light.

6.5 Nature and composition of immediate packaging

The tablets are packed in Aluminium foil PVC blisters (each strip containing 10 tablets). Pack size of 100 tablets.

or

White high density polyethylene tub (30 and 1,000 tablets) with white low density polyethylene tamper evident lid (push fit).

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

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

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
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Surrey
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8. MARKETING AUTHORISATION NUMBER

Vm 42058/4083

9. DATE OF FIRST AUTHORISATION

29 November 1991

10. DATE OF REVISION OF THE TEXT

February 2022

Approved 11 February 2022

A handwritten signature in black ink, appearing to read "Hunter.", is positioned below the approval date.