Zoetis UK Limited

Telephone:0345 300 8034

Website:www.zoetis.co.uk

Email:customersupportuk@zoetis.com

Medrone V Tablets 2 mg and 4 mg

Species: Cats, Dogs

Therapeutic indication:Pharmaceuticals: Anti-inflammatory preparations: Oral: Other steroids

Active ingredient: Methylprednisolone

Product: Medrone™ V Tablets

Product index: Medrone V Tablets

Incorporating:

Presentation

2 mg tablets: oval, scored pink tablets containing 2 mg of methylprednisolone.

4 mg tablets: half oval, elliptical white tablets containing 4 mg of methylprednisolone.

Uses

Oral glucocorticoid for dogs and cats.

Medrone V Tablets are indicated 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. autoimmune disorders.

Dosage and administration

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 individual's 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 to 5 kg	1 mg
5 to 9 kg	2 mg
9 to 18 kg	2 to 4 mg
18 to 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 own discretion, use alternate day therapy in order to maintain minimal effective therapy of chronic conditions; published data and scientific opinion would suggest that dogs should be treated on every alternative morning and cats on every alternate evening.

Contra-indications, warnings, etc

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

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.

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-Pituitreal-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. 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.

Concurrent administration of barbiturates, phenylbutazone, phenytoin or rifampicin may enhance the metabolism and reduce the effect of corticosteriods.

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

Wash hands after use.

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

Pharmaceutical precautions

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

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

Keep out of the sight and reach of children.

For animal treatment only.

Legal category

Legal category:POM-V

Packaging quantities

2 mg: Packs of 30 or 1000 tablets in bottles, and 100 tablets in blister packs.

4 mg: Packs of 30 or 1000 tablets in bottles.

Not all pack sizes may be marketed.

Further information

Medrone V Tablets can be used to initiate anti-inflammatory treatment or to continue therapy after an injectable corticosteroid has been given.

Methylprednisolone has achieved a clinically acceptable split between glucocorticoid activity and undesired mineralocorticoid activity. Weight for weight, methylprednisolone has five times the anti-

inflammatory activity of hydrocortisone and 1.25 times the anti-inflammatory activity of prednisolone but, unlike the latter two corticosteroids, has virtually no mineralocorticoid activity; therefore, the risk of mineralocorticoid-induced side effects is relatively low.

Marketing Authorisation Number

Medrone V Tablets 2 mg	Vm 42058/5227
Medrone V Tablets 4 mg	Vm 42058/5226

Significant changes

GTIN

GTIN description:2 mg x 1000:

GTIN:05013457085396

GTIN description:4 mg x 1000:

GTIN:05013457085389