PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON) AND THE IMMEDIATE PACKAGE (BOTTLE LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Medrone™ V Tablets 2 mg

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablet contains methylprednisolone 2 mg.

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

30 tablets (bottle only)

100 tablets (blisters only)

1000 tablets (bottle only)

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

Read the package leaflet before use for full indications and detailed guidance on dosage.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable

9. SPECIAL WARNING(S), IF NECESSARY

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.

10. EXPIRY DATE

EXP: [MM/YYYY]

11. SPECIAL STORAGE CONDITIONS

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

Keep the container in the outer carton.

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

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 42058/4083

17. MANUFACTURER'S BATCH NUMBER

Batch No.:

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Medrone™ V Tablets 2 mg

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

3. EXPIRY DATE

EXP: [MM/YYYY]

4. BATCH NUMBER

Batch No.:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

PACKAGE LEAFLET FOR:

Medrone™ V Tablets 2 mg

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

Site of batch release
Pfizer Italia S.r.l.
63100 Marino del Tronto
Ascoli Picenco
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Medrone™ V Tablets 2 mg

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

Each tablet contains 2 mg methylprednisolone. Each 2 mg tablet also contains 0.0007 mg amaranth (E123) and 0.0042 mg erythrosine (E127).

Medrone V Tablets 2 mg are oval, scored pink uncoated tablets.

4. INDICATION(S)

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, musculoskeletal conditions, ocular/otic inflammatory conditions and other inflammatory/allergic conditions that are likely to respond to corticosteroid therapy e.g. auto-immune disorders.

5. CONTRAINDICATIONS

Systemic corticosteroid therapy is generally contraindicated in patients with renal disease and diabetes mellitus.

6. ADVERSE REACTIONS

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 GI 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.

If you notice any serious effects or other effects not mentioned in the package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs and cats.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For oral 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 – 5 kg	1 mg
5 – 9 kg	2 mg
9 – 18 kg	2 to 4 mg
18 – 36 kg	4 to 8 mg

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

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

12. SPECIAL WARNINGS

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.
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.
Significant adverse effects are unlikely following a single accidental overdose.

User Warnings:
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 closure when dispensing this product.

Keep out of the sight and reach of children.

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

February 2022

15. OTHER 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.

Medrone V Tablets are supplied in Aluminium foil PVC blisters (each strip containing 10 tablets), in a pack size of 100 tablets, or tubs containing 30 or 1000 tablets. Not all pack sizes may be marketed.

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Vm 42058/4083

Approved 11 February 2022