MEDROL- methylprednisolone tablet
Zoetis Inc.

Medrol®
methylprednisolone tablets

For Oral Use
In Dogs and Cats

Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Methylprednisolone, a potent anti-inflammatory steroid synthesized and developed in the Research Laboratories of The Upjohn Company is the 6-methyl derivative of prednisolone. It has a greater anti-inflammatory potency than prednisolone and even less tendency than prednisolone to induce sodium and water retention. Its advantage over the older corticoids lies in its ability to achieve equal anti-inflammatory effect with lower dose, while at the same time enhancing the split between anti-inflammatory and mineralocorticoid activities.

INDICATIONS

The indications for MEDROL Tablets are the same as those for other anti-inflammatory steroids and comprise the various collagen, dermal, allergic, ocular, otic, and musculoskeletal conditions known to be responsive to the anti-inflammatory corticosteroids. Representative of the conditions in which the use of steroid therapy and the benefits to be derived therefrom have had repeated confirmation in the veterinary literature are: (1) dermal conditions, such as non-specific eczema, summer dermatitis, and burns; (2) allergic manifestations, such as acute urticaria, allergic dermatitis, drug and serum reactions, bronchial asthma, and pollen sensitivities; (3) ocular conditions, such as iritis, iridocyclitis, secondary glaucoma, uveitis, and chorioretinitis; (4) otic conditions, such as otitis externa; (5) musculoskeletal conditions, such as myositis, rheumatoid arthritis, osteoarthritis, and bursitis; (6) various chronic or recurrent diseases of unknown etiology such as ulcerative colitis and nephrosis.

In acute adrenal insufficiency, MEDROL may be effective because of its ability to correct the defect in carbohydrate metabolism and relieve the impaired diuretic response to water characteristic of primary or secondary adrenal insufficiency. However, because this agent lacks significant mineralocorticoid activity, the parent hormones, SOLU-CORTEF® containing hydrocortisone sodium succinate, CORTEF® containing hydrocortisone, or cortisone should be used when salt retention is indicated.

CONTRAINDICATIONS

MEDROL Tablets like prednisolone, are contraindicated in animals with arrested tuberculosis, peptic ulcer, acute psychoses, and Cushingoid syndrome. The presence of diabetes, osteoporosis, chronic psychotic reactions, predisposition to thrombophlebitis, hypertension, congestive heart failure, renal insufficiency, and active tuberculosis necessitates carefully controlled use. Some of the above conditions occur only rarely in dogs and cats but should be kept in mind.

WARNINGS

Not for human use.

Clinical and experimental data have demonstrated that corticosteroids administered orally or

parenterally to animals may induce the first stage of parturition when administered during the last trimester of pregnancy and may precipitate premature parturition followed by dystocia, fetal death, retained placenta, and metritis.

Additionally, corticosteroids administered to dogs, rabbits and rodents during pregnancy have resulted in cleft palate in offspring. Corticosteroids administered to dogs during pregnancy have also resulted in other congenital anomalies including deformed forelegs, phocomelia, and anasarca.

PRECAUTIONS

Because of its inhibitory effect on fibroplasia, methylprednisolone may mask the signs of infection and enhance dissemination of the infecting organism. Hence, all animal patients receiving methylprednisolone should be watched for evidence of intercurrent infection. Should infection occur, it must be brought under control by use of appropriate antibacterial measures, or administration of methylprednisolone should be discontinued.

MEDROL Tablets, like prednisolone and other adrenocortical steroids is a potent therapeutic agent influencing the biochemical behavior of most, if not all, tissues of the body. Because this anti-inflammatory steroid manifests little sodium-retaining activity, the usual early sign of cortisone or hydrocortisone overdosage (ie, increase in body weight due to fluid retention) is not a reliable index of overdosage. Hence, recommended dose levels should not be exceeded, and all animal patients receiving MEDROL should be under close medical supervision. All precautions pertinent to the use of prednisolone apply to methylprednisolone. Moreover, the veterinarian should endeavor to keep informed of current studies with MEDROL as they are reported in the veterinary literature.

ADVERSE REACTIONS

With therapeutically equivalent doses, the likelihood of occurrence of troublesome side effects is less with methylprednisolone than with prednisolone; moreover, side effects actually have been conspicuously absent during clinical trials with MEDROL Tablets in dogs and cats. However, methylprednisolone is similar to prednisolone in regard to kinds of side effects and metabolic alterations to be anticipated when treatment is intensive or prolonged. In animal patients with diabetes mellitus, use of methylprednisolone may be associated with an increase in the insulin requirement. Negative nitrogen balance may occur, particularly in animals that require protracted maintenance therapy; measures to counteract persistent nitrogen loss include a high protein intake and the administration when indicated, of a suitable anabolic agent. Excessive loss of potassium, like excessive retention of sodium, is not likely to be induced by effective maintenance doses of MEDROL. However, these effects should be kept in mind and the usual regulatory measures employed as indicated. Ecchymotic manifestations, *while not noted during the clinical evaluation* in dogs and cats, may occur. If such reactions do occur and are serious, reduction in dosage or discontinuance of methylprednisolone therapy may be indicated. Concurrent use of daily oral supplements of ascorbic acid may be of value in helping to control ecchymotic tendencies.

Since methylprednisolone, like prednisolone, suppresses endogenous adrenocortical activity, *it is highly important that the animal patient receiving MEDROL be under careful observation, not only during the course of treatment but for some time after treatment is terminated. Adequate adrenocortical supportive therapy with cortisone or hydrocortisone, and including ACTH, must be employed promptly if the animal is subjected to any unusual stress such as surgery, trauma, or severe infection.*

DOSAGE AND ADMINISTRATION

The keystone of satisfactory therapeutic management with MEDROL Tablets, as with its steroid predecessors, is individualization of dosage in reference to the severity of the disease, the anticipated duration of steroid therapy, and the animal patient's threshold or tolerance for steroid excess.

The prime objective of steroid therapy should be to achieve a satisfactory degree of control with a minimum effective daily dose.

The dosage recommendations are suggested ***average total daily doses*** *and are intended as guides.* As with other orally administered corticosteroids, the total daily dose of MEDROL should be given in equally divided doses. The initial suppressive dose level is continued until a satisfactory clinical response is obtained, a period usually of 2 to 7 days in the case of musculoskeletal diseases, allergic conditions affecting the skin or respiratory tract, and ocular inflammatory diseases. If a satisfactory response is not obtained in 7 days, reevaluation of the case to confirm the original diagnosis should be made. As soon as a satisfactory clinical response is obtained, the daily dose should be reduced gradually, either to termination of treatment in the case of acute conditions (eg, seasonal asthma, dermatitis, acute ocular inflammations) or to the minimal effective maintenance dose level in the case of chronic conditions (eg, rheumatoid arthritis). In chronic conditions, and in rheumatoid arthritis especially, it is important that the reduction in dosage from initial to maintenance dose levels be accomplished slowly. The maintenance dose level should be adjusted from time to time as required by fluctuation in the activity of the disease and the animal's general status. Accumulated experience has shown that the long-term benefits to be gained from continued steroid maintenance are probably greater the lower the maintenance dose level. In rheumatoid arthritis in particular, maintenance steroid therapy should be at the lowest possible level.

Important: In the therapeutic management of animal patients with chronic diseases such as rheumatoid arthritis, methylprednisolone should be regarded as a highly valuable adjunct, to be used in conjunction with but not as replacement for standard therapeutic measures.

Average total daily oral doses for dogs and cats:

5 to 15 lb body wt	2 mg
15 to 40 lb body wt	2 to 4 mg
40 to 80 lb body wt	4 to 8 mg

The total daily dose should be given in divided doses, 6 to 10 hours apart.

HOW SUPPLIED

Veterinary MEDROL Tablets are compressed cross-scored tablets available in bottles of 500.

Each 4 mg tablet contains 4 mg methylprednisolone.

Store at controlled room temperature 20° to 25° C (68° to 77° F).

Manufactured by:
Pfizer Inc
Ascoli, Italy

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

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PRINCIPAL DISPLAY PANEL - 4 mg Tablet Bottle Label

500 Tablets

Medrol®

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4 mg

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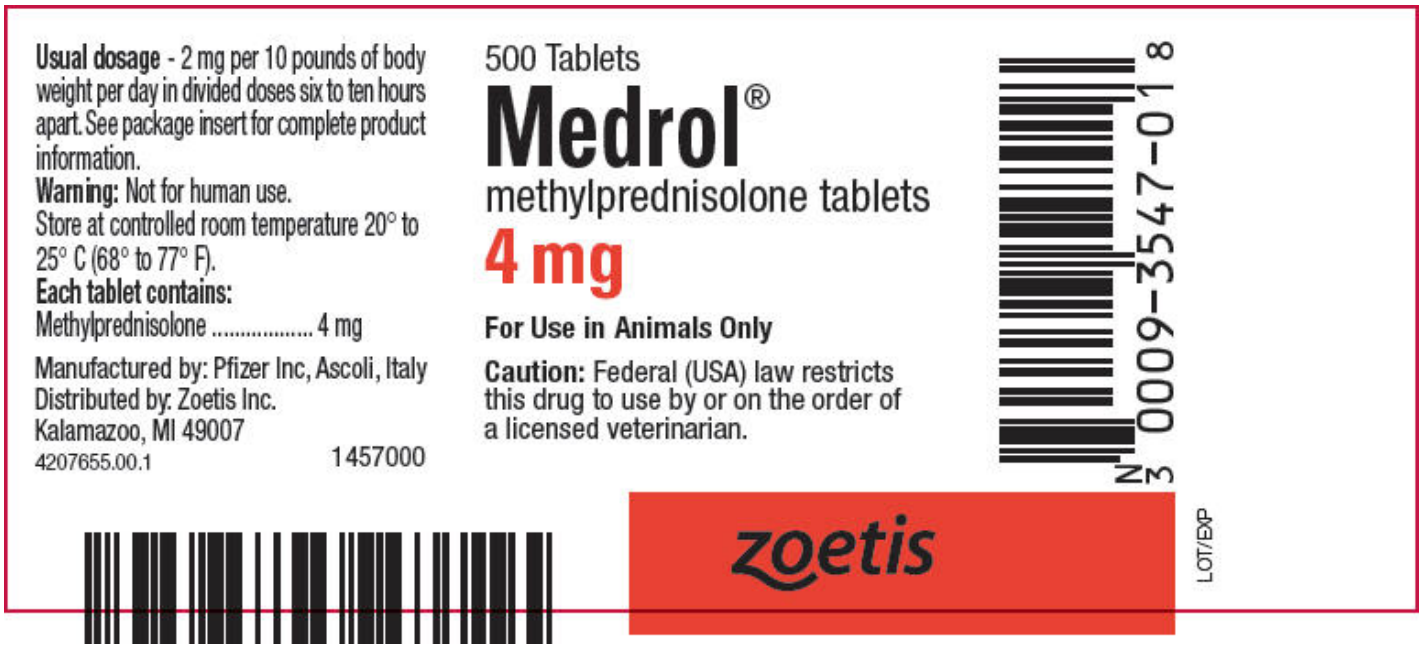

MEDROL

methylprednisolone tablet

Product Information			
Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:54771-3547
Route of Administration	ORAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
METHYLPREDNISOLONE (UNII: X4W7ZR7023) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE	4 mg

Product Characteristics			
Color	WHITE	**Score**	4 pieces
Shape	OVAL	**Size**	8mm
Flavor		**Imprint Code**	Medrol;4
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-3547-1	500 in 1 BOTTLE, GLASS		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA011403	07/30/1958	

Labeler - Zoetis Inc. (828851555)

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