METHYLPREDNISOLONE- methylprednisolone tablet
Cronus Pharma LLC

Methylprednisolone Tablets, USP

For Oral Use in Dogs and Cats Only
CAUTION: Federal law restricts this drug to use by or on the order of a licensed veterinarian.

DESCRIPTION

Methylprednisolone, a potent glucocorticoid and anti-inflammatory agent, is a synthetic 6-methyl derivative of prednisolone. It has a greater anti-inflammatory potency than prednisolone and is less likely to induce sodium and water retention. Its advantage over the older corticoids lies in its ability to achieve equal anti-inflammatory effect with a lower dose, while at the same time enhancing the split between anti-inflammatory and mineralocorticoid activities. [1,2,3]

Each tablet contains 1mg, 2mg or 4mg of methylprednisolone.

ACTIONS

Glucocorticoids exert a regulatory influence on lymphocytes, erythrocytes and eosinophils of the blood and on the structure and function of lymphoid tissues.[1,4,5] A primary feature of the glucocorticoids is their anti-inflammatory activity with minimum sodium and water retention which is often associated with the mineralocorticoids. [1,2,3,4,5,6] Glucocorticoids not only inhibit the early phases of the inflammatory process (edema, fibrin deposition, capillary dilation, migration of leukocytes into the inflamed area and phagocytic activity) but also the later manifestations (capillary proliferation, fibroblast proliferation and deposition of collagen). [3,4,6] The exact mechanism is not known, but the glucocorticoids obviously suppress normal tissue response to injury and alleviate symptoms from many conditions. [2]

INDICATIONS

The indications 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:

Dermal conditions, such as non-specific eczema and summer dermatics. [1,2,4]

Allergic manifestations, such as acute urticaria, allergic dermatitis, drug and serum reactions, non-specific pruritus, bronchial asthma and pollen sensitivities. [1,2,3,4,5]

Ocular Conditions, such as iritis, iridocyclitis, secondary glaucoma, uveitis and chlorioretinitis. [1,3,4,5]

Otic Conditions, such as otitis externa. [4]

Musculoskeletal Conditions, such as myositis, rheumatoid arthritis, osteoarthritis and bursitis. [1,2,3,4,5]

Various chronic or recurrent diseases of unknown etiology such as ulcerative colitis and nephrosis. [1,2,3,5]

In acute adrenal insufficiency, methylprednisolone 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, hydrocortisone sodium succinate or cortisone should be used when salt retention is indicated.

CONTRAINDICATIONS

Do not use in viral infections. Methylprednisolone, like prednisolone, is contraindicated in animals with arrested tuberculosis, peptic ulcer, acute psychoses, corneal ulcer 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.

WARNING

Because of its inhibitory effect on fibroplasia, methylprednisolone may mask the signs of infection and enhance dissemination of the infecting organism. Hence all animals 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.

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, corticosteroid administered to dogs, rabbits and rodents during pregnancy have produced cleft palate. Other congenital anomalies including deformed forelegs, phocomella and anasarca have been reported in offspring of dogs which received corticosteroids during pregnancy.

PRECAUTIONS

Methylprednisolone, 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 (i.e., increase in body weight due to fluid retention) is not a reliable index of overdosage. Hence, recommended

dosage levels should not be exceeded, and all animals receiving methylprednisolone 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 methylprednisolone as they are reported in the veterinary literature.

Use of corticosteroids, depending on dose, duration and specific steroid, may result in inhibition of endogenous steroid production following drug withdrawal. In patients presently receiving or recently withdrawn from systemic corticosteroid treatments, therapy with a rapid acting corticosteroid should be considered in usually stressful situations.

ADVERSE REACTIONS

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 animals 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 methylprednisolone. 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.

Side effects, such as SAP and SGPT enzyme elevations, weight loss, anorexia, polydipsia and polyuria have occurred following the use of synthetic corticosteroids in dogs. Vomiting and diarrhea (occasionally bloody) have been observed in dogs and cats. Cushing’s syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

To report suspected adverse drug events, for technical assistance or to obtain a copy of the Safety Data Sheet, contact Cronus Pharma LLC at 1-844-227-6687 and 1-844-2-CRONUS. For additional information about adverse drug experience reporting for animal drugs, contact FDA at 1-888-FDA-VETS or http://www.fda.gov/reportanimalae.

DOSAGE AND ADMINISTRATION

The keystone of satisfactory therapeutic management with methylprednisolone, 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’s threshold or tolerance for steroid excess. The prime objective of steroid therapy should be 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 methylprednisolone tablets 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, re-evaluation 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 (e.g., seasonal asthma, dermatitis, acute ocular inflammations) or to the minimal effective maintenance dose level in the case of chronic conditions (e.g., 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 animals 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 a replacement for standard therapeutic measures.

RECOMMENDED DOSAGE SCHEDULE

Average total daily doses for dogs and cats are as follows:
5 to 15 lb body weight.....2 mg
15 to 40 lb body weight.....2 to 4 mg
40 to 80 lb body weight.....4 to 8 mg
Use half tablets as needed to achieve the desired dose
The total daily dose should be given in doses, 6 to 10 hours apart.

HOW SUPPLIED

Methylprednisolone tablets, USP 1mg, 2mg are yellow round shaped scored tablets available in bottles of 100 and 500.
Methylprednisolone tablets, USP 4mg are yellow oval shaped scored tablets available in bottles of 100 and 500.

Each 1mg tablet contains 1mg methylprednisolone, USP.
Each 2mg tablet contains 2mg methylprednisolone, USP.
Each 4mg tablet contains 4mg methylprednisolone, USP.

Split tablets should be used within 90 days.
Store at controlled room temperature 20° to 25°C (68° to 77°F).

REFERENCES

1. Osol, A., ed., 1980. Remington's Pharmaceutical Sciences, 16th Edition. Mack Publishing Company, Easton, PA. 898-901, 908.
2. Martindale, The Extra pharmacopoeia, 27th Edition, 1977. The Pharmaceutical Press, London, England. 389-396, 424-425
3. Gilman, A.G., L.S. Goodman and A. Gilman, eds., 1980. The Pharmacological Basis of Therapeutics, 6th Edition. Macmillan Publishing Co., Inc., New York. NY. 1470-1496.
4. Booth, N.H and L.E McDonald, eds., 1982. Veterinary Pharmacology and Therapeutics, 5th Edition. The lowa State University Press, Ames, IA. 553-570.
5. Dipalma, J.R., ed., 1976. Basic Pharmacology in Medicine, McGraw-Hill, Inc., St. Louis, MO 328-337.
6. Kirk, R.W., ed., 1980. Current Veterinary Therapy VII, Small Animal Practice. W.B Saunders Company. Philadelphia, PA. 497-500, 992-994.

KEEP OUT OF REACH OF CHILDREN

Approved by FDA under NADA # 135-771

Code: 4206162/TS/DRUGS/2023

Manufactured for:
Cronus Pharma LLC,
East Brunswick, NJ 08816.
Contact No: 1-844-227-6687
(1-844-2-CRONUS)

Made in India
Sepetember 2023

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 69043-040-10

Methylprednisolone Tablets, USP 4 mg

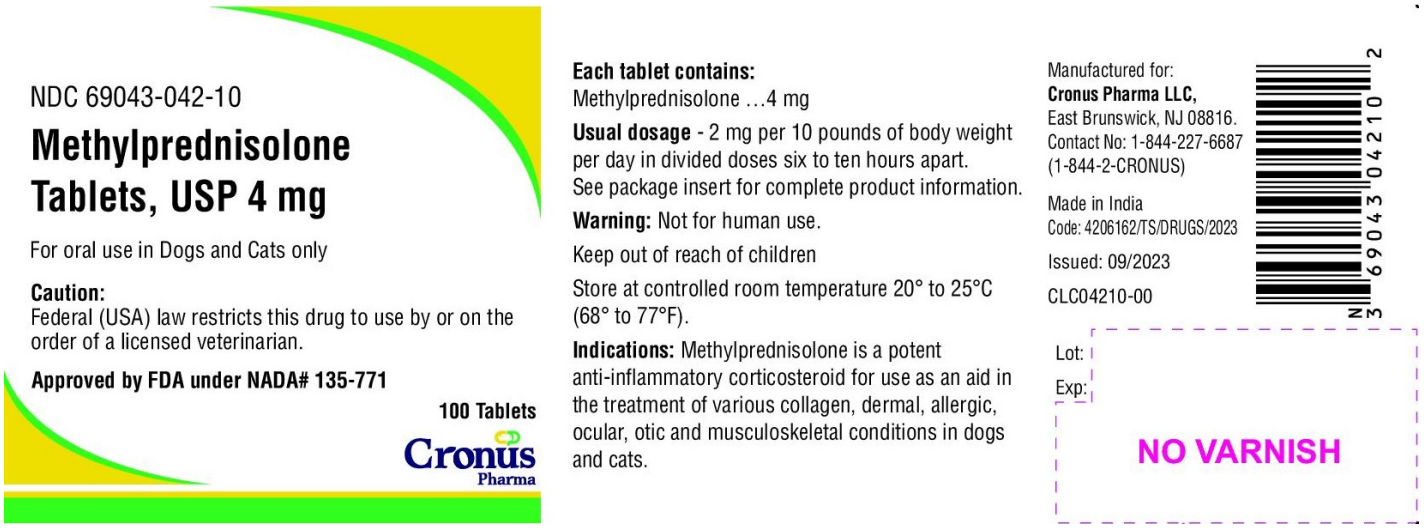
For oral use in Dogs and Cats only

Caution:

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

Approved by FDA under NADA# 135-771

100 Tablets



METHYLPREDNISOLONE

methylprednisolone tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	**Item Code (Source)**	NDC:69043-042
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	yellow	**Score**	2 pieces
Shape	OVAL	**Size**	12mm
Flavor	VANILLA	**Imprint Code**	C62
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69043-042-10	100 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA135771	01/02/2024	

Labeler - Cronus Pharma LLC (079421067)

Registrant - Cronus Pharma Specialities India Private Limited (876818318)

Establishment

Name	Address	ID/FEI	Business Operations
Cronus Pharma Specialities India Private Limited		876818318	analysis, manufacture, label, pack

Revised: 1/2024 Cronus Pharma LLC