

TRIAMCINOLONE ACETONIDE- triamcinolone acetonide tablet
Boehringer Ingelheim Vetmedica, Inc.

Triamcinolone Acetonide Tablets

NADA 137-694, Approved by FDA

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

Triamcinolone acetonide is a highly potent synthetic glucocorticoid and anti-inflammatory agent.¹ Its advantage over the older corticoids lies in its ability to achieve equal anti-inflammatory effect with a lower dose.^{2 3 4} Triamcinolone has very weak sodium-retaining effects and is probably the least electrolyte-retaining compound of the corticosteroid group.^{2 4} Triamcinolone has a plasma half-life of approximately 300 minutes and is classified as an intermediate acting glucocorticoid, whereas the acetonide salt has a longer duration of action and a higher lipid-water distribution coefficient.^{1 2 3 4}

Indications

Triamcinolone acetonide is a highly potent glucocorticoid effective in the treatment of inflammation and related disorders in dogs and cats. It is indicated in the management and treatment of acute arthritis and allergic and dermatologic disorders.

Dosage and Administration

The keystone of satisfactory therapeutic management with triamcinolone acetonide, as with other steroids, 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 to achieve a satisfactory degree of control with a minimum effective dose.

The initial suppressive dose level of 0.5 -1.0 mg per 10 pounds of body weight daily should be administered until a satisfactory clinical response is obtained, a period not to exceed 14 days. If a satisfactory response is not obtained in 14 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). Symptoms of adrenal insufficiency following withdrawal may persist for several days, weeks or years. Some cases have resulted in death. To minimize the adverse effects from withdrawal or reduction in dosage, cautiously decrease dosage in a gradual manner. In dogs, dosing in the morning may also be beneficial in minimizing effects because nocturnal pituitary/adrenal activity will be less inhibited. 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. Maintenance dosage levels of 0.125-0.25 mg per 10 pounds of body weight daily are recommended. 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, triamcinolone 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:

Body Weight	Initial Daily Dosage	Maintenance Daily Dosage
5 lbs	0.25 to 0.5 mg	0.0625 to 0.125 mg
10 lbs	0.5 to 1.0 mg	0.125 to 0.25 mg
20 lbs	1.0 to 2.0 mg	0.25 to 0.50 mg
30 lbs	1.5 to 3.0 mg	0.375 to 0.75 mg
60 lbs	3.0 to 6.0 mg	0.75 to 1.50 mg

Contraindications

Do not use in viral infections. Except for emergency therapy, do not use in animals with tuberculosis, chronic nephritis, cushingoid syndrome and peptic ulcers. Existence of congestive heart failure, diabetes and osteoporosis are relative contraindications.

Warning

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 produced cleft palate. Other congenital anomalies including deformed forelegs, phocomelia and anasarca have been reported in the offspring of dogs which received corticosteroids during pregnancy.

Precautions

Because of its inhibitory effect on fibroplasia, triamcinolone may mask the signs of infection and enhance dissemination of the infecting organism. Hence, all animals receiving triamcinolone 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 triamcinolone should be discontinued.

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 triamcinolone acetate should be under close medical supervision.

Use of corticosteroids may result in the inhibition of endogenous steroid production which sometimes persists for weeks following drug withdrawal. In patients presently receiving or recently withdrawn from corticosteroid treatments, administration of a rapid acting corticosteroid before, during and after an unusually stressful situation is recommended.

Single or multiple doses of 1 mg/kg of a corticosteroid induced hepatopathy in the dog and rabbit in a study by Rogers and Ruebner in 1977.⁴ The condition was determined in the dog by a biopsy of the liver and was accompanied by elevated serum glutamic-pyruvic transaminase, SAP and SGGT (in some dogs) and increased bromsulphalein retention.

Adverse Reactions

As with the use of any corticosteroid, side effects and metabolic alterations can be anticipated when

treatment is intensive or prolonged. In animals with diabetes mellitus, use of triamcinolone acetonide may be associated with an increase in the insulin requirement. Negative nitrogen balance may occur, particularly in animals that require protracted maintenance therapy.^{3 4 5} Polydipsia or polyuria may occur with high dosage or frequent administration. The likelihood of their occurrence may be minimized by giving as brief a course of corticosteroid therapy as possible, and by waiting for the reappearance of symptoms before repeating therapy. If polydipsia or polyuria should occur, therapy should then be resumed at a lower dosage level.

Other adverse reactions that have occurred with the use of corticosteroids are SAP and SGPT enzyme elevations, weight loss, anorexia, vomiting and diarrhea (occasionally bloody). Anaphylactoid reactions have occasionally been seen following administration. Cushing's syndrome in dogs has been reported in association with prolonged or repeated steroid therapy.

To report suspected adverse reactions, to obtain a Material Safety Data Sheet (MSDS) or for technical assistance, call 1-866-638-2226.

Clinical Pharmacology

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 dilatation, 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

As with other adrenal steroids, triamcinolone acetonide has been found useful in alleviating the pain and lameness associated with acute localized arthritic conditions and generalized arthritic conditions. Glucocorticoids have been used successfully to treat traumatic arthritis, osteoarthritis and generalized arthritic conditions in dogs. Remission of musculoskeletal conditions may be permanent, or symptoms may recur, depending on the cause and extent of structural degeneration.^{1 2 3 4 5} Glucocorticoids also relieve pruritus and inflammation of allergic dermatitis, acute moist dermatitis, dry eczema, urticaria, bronchial asthma, pollen sensitivities and otitis externa in dogs and allergic dermatitis and moist and dry eczema in cats. Symptoms may be expected to recur if the cause of the allergic reaction is still present, in which case retreatment may be indicated. In treating acute hypersensitivity reactions, such as anaphylactic shock, appropriate treatment such as intravenous prednisolone sodium succinate should be used.^{1 2 3 4 5}

In dogs and cats moribund from overwhelmingly severe infections for which antibacterial therapy is available (e.g., critical pneumonia, pyometritis), a glucocorticoid may be lifesaving, acting to inhibit the inflammatory reaction, which itself may be lethal; preventing vascular collapse and preserving the integrity of the blood vessels; modifying the animal's reaction to drugs; and preventing or reducing the exudative reaction which often complicates certain infections. As supportive therapy, it improves the general attitude of the animal being treated. All necessary procedures for the establishment of a bacterial diagnosis should be carried out whenever possible before institution of therapy. Corticosteroid therapy in the presence of infection should be administered for the shortest possible time compatible with maintenance of an adequate response, and antibacterial therapy should be continued for at least three days after the hormone has been withdrawn. Combined hormone and antibacterial therapy does not obviate the need for indicated surgical treatment.^{1 2 3 4 5 6}

Storage

Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (59° and 86°F).

How Supplied

Triamcinolone Acetonide Tablets are available in two strengths, 0.5 and 1.5 mg.

NDC-0010-6876-01 - 0.5 mg - 1,000 tablets

NDC-0010-6877-01 - 1.5 mg - 500 tablets

References

1. Osol, A., ed., 1980. *Remington's Pharmaceutical Sciences*, 16th Edition. Mack Publishing Company, Easton, PA. 898-901, 911.
2. *Martindale, The Extra Pharmacopoeia*, 27th Edition, 1977. The Pharmaceutical Press, London, England. 389-396, 432-433.
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 Iowa 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.

Manufactured for:

Boehringer Ingelheim Vetmedica, Inc.

St. Joseph, MO 64506 U.S.A.

Revised 06/2012

Bottle Label, 0.5 mg, 1000 tablets

NDC 0010-6876-01
Triamcinolone Acetonide Tablets
0.5 mg
Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Net Contents: 1000 Tablets
NADA 137-694, Approved by FDA

0.5 mg

Each tablet contains: 0.5 mg triamcinolone acetonide.
Indications: Triamcinolone acetonide is a highly potent glucocorticoid effective in the treatment of inflammation and related disorders in dogs and cats. It is indicated in the management and treatment of acute arthritis and allergic and dermatologic disorders.
Dosage: 0.5 to 1.0 mg per 10 pounds of bodyweight daily.
Keep out of reach of children.
For oral use in dogs and cats only.
For use in animals only.
Refer to folded package insert attached to this container for complete product information.
Storage: Store at 20° to 25°C (68° to 77°F), excursions permitted between 15° and 30°C (between 59° and 86°F).

Manufactured for:
Boehringer Ingelheim Vetmedica, Inc.
St. Joseph, MO 64506 U.S.A.
687601-02 80737572 80728859, R.0

Boehringer Ingelheim

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0 12313 68765 6

Bottle Label, 1.5 mg, 500 tablets

NDC 0010-6877-01
Triamcinolone Acetonide Tablets
 1.5 mg
 Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
 Net Contents: 500 Tablets
 NADA 137-694, Approved by FDA

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Manufactured for:
 Boehringer Ingelheim Vetmedica, Inc.
 St. Joseph, MO 64506 U.S.A.
 687607-02 80737580 80728883, R.0



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0 12313 68763 2

TRIAMCINOLONE ACETONIDE				
triamcinolone acetonide tablet				
Product Information				
Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-6876	
Route of Administration	ORAL			
Active Ingredient/Active Moiety				
Ingredient Name		Basis of Strength	Strength	
TRIAMCINOLONE ACETONIDE (UNII: F446C597KA) (TRIAMCINOLONE ACETONIDE - UNII:F446C597KA)		TRIAMCINOLONE ACETONIDE	0.5 mg	
Product Characteristics				
Color	PINK	Score	4 pieces	
Shape	ROUND	Size	5mm	
Flavor		Imprint Code	0;5;251	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-6876-01	1000 in 1 BOTTLE, PLASTIC		
Marketing Information				
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date	
NADA	NADA137694	04/03/2000		

TRIAMCINOLONE ACETONIDE

triamcinolone acetonide tablet

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:0010-6877
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
TRIAMCINOLONE ACETONIDE (UNII: F446C597KA) (TRIAMCINOLONE ACETONIDE - UNII:F446C597KA)	TRIAMCINOLONE ACETONIDE	1.5 mg

Product Characteristics

Color	PINK	Score	4 pieces
Shape	ROUND	Size	8mm
Flavor		Imprint Code	1;5;252
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0010-6877-01	500 in 1 BOTTLE, PLASTIC		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA137694	04/03/2000	

Labeler - Boehringer Ingelheim Vetmedica, Inc. (007134091)

Revised: 4/2013

Boehringer Ingelheim Vetmedica, Inc.