

DEPO-MEDROL- methylprednisolone acetate injection, suspension
Zoetis Inc.

Depo-Medrol®

(methylprednisolone acetate injectable suspension)

20 mg per mL and 40 mg per mL

For Use in Animals Only

Caution

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

DESCRIPTION

These preparations are recommended for intramuscular and intrasynovial injection in horses and dogs, and intramuscular injection in cats. DEPO-MEDROL is available in two concentrations, 20 mg per mL and 40 mg per mL. Each mL of these preparations contains:

	20 mg	40 mg
Methylprednisolone acetate	20 mg	40 mg
Polyethylene glycol 3350	29.6 mg	29.1 mg
Sodium chloride	8.9 mg	8.7 mg
Myristyl-gamma-picolinium chloride added as preservative	0.197 mg	0.194 mg

When necessary, pH was adjusted with sodium hydroxide and/or hydrochloric acid. The chemical name for methylprednisolone acetate is pregna-1,4-diene-3,20-dione, 21-(acetyloxy)-11,17-dihydroxy-6-methyl-, (6 α ,11 β)-

CLINICAL PHARMACOLOGY

Metabolic and Hormonal Effects

Methylprednisolone, an anti-inflammatory steroid synthesized and developed in the Research Laboratories of The Upjohn Company, is the 6-methyl derivative of prednisolone. Exceeding prednisolone in anti-inflammatory potency and having even less tendency than prednisolone to induce sodium and water retention, methylprednisolone offers the advantage over older corticosteroids of affording equally satisfactory anti-inflammatory effect with the use of lower doses and with an enhanced split between anti-inflammatory and mineralocorticoid activities. Estimates of the relative potencies of methylprednisolone and prednisolone range from 1.13 to 2.1, with an average of 1.5. In anti-inflammatory activity, as measured by the granuloma pouch assay, methylprednisolone is twice as active as prednisolone. In

mineralocorticoid activity (ie, the capacity to induce retention of sodium and water in the adrenalectomized rat) methylprednisolone is slightly less active than prednisolone. The duration of plasma steroid levels following rapid intravenous injection in intact dogs is appreciably longer for methylprednisolone than for prednisolone, the respective "half-life" value for the two steroids being 80.9 ± 7.5 minutes for methylprednisolone and 71.3 ± 1.7 minutes for prednisolone.

While the effect of parenterally administered DEPO-MEDROL is prolonged, it has the same metabolic and anti-inflammatory actions as orally administered methylprednisolone acetate.

INDICATIONS AND USAGE

Musculoskeletal Conditions

As with other adrenal steroids, DEPO-MEDROL has been found useful in alleviating the pain and lameness associated with acute localized arthritic conditions and generalized arthritic conditions. It has been used successfully to treat rheumatoid arthritis, traumatic arthritis, osteoarthritis, periostitis, tendinitis, synovitis, tenosynovitis, bursitis, and myositis of horses; traumatic arthritis, osteoarthritis, and generalized arthritic conditions of dogs. Remission of musculoskeletal conditions may be permanent, or symptoms may recur, depending on the cause and extent of structural degeneration.

Allergic Conditions

This preparation is especially beneficial in relieving pruritus and inflammation of allergic dermatitis, acute moist dermatitis, dry eczema, urticaria, bronchial asthma, pollen sensitivities and otitis externa in dogs; allergic dermatitis and moist and dry eczema in cats. Onset of relief may begin within a few hours to a few days following injection and may persist for a few days to six weeks. 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, intravenous SOLU-DELTA-CORTEF® Sterile Powder containing prednisolone sodium succinate, as well as other appropriate treatments, should be used.

Overwhelming Infections with Severe Toxicity

In dogs and cats moribund from overwhelmingly severe infections for which antibacterial therapy is available (eg, critical pneumonia, pyometritis), DEPO-MEDROL 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 patient'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.

Other Conditions

In certain conditions where it is desired to reduce inflammation, vascularization, fibroblastic infiltration, and scar tissue, the use of DEPO-MEDROL should be considered. Snakebite of dogs also is an indication for the use of this suspension because of its anti-toxic, anti-shock, and anti-inflammatory activity. It is particularly effective in reducing swelling and preventing sloughing. Its employment in the treatment of such conditions is recommended as a supportive measure to standard procedures and time-honored treatments and will give comfort to the animal and hasten complete recovery.

CONTRAINDICATIONS

Systemic therapy with methylprednisolone acetate, as with other corticoids, is contraindicated in animals with arrested tuberculosis, peptic ulcer, and Cushing's syndrome. The presence of active tuberculosis, diabetes mellitus, osteoporosis, renal insufficiency, predisposition to thrombophlebitis, hypertension, or congestive heart failure necessitates carefully controlled use of corticosteroids. Intrasyovial, intratendinous, or other injections of corticosteroids for local effect are contraindicated in the presence of acute infectious conditions. Exacerbation of pain, further loss of joint motion, with fever and malaise following injection may indicate that the condition has become septic. Appropriate antibacterial therapy should be instituted immediately.

WARNING

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.

Not for human use. Do not use in horses intended for human consumption.

PRECAUTIONS

DEPO-MEDROL exerts an inhibitory influence on the mechanisms and the tissue changes associated with inflammation. Vascular permeability is decreased, exudation diminished, and migration of the inflammatory cells markedly inhibited. In addition, systemic manifestations such as fever and signs of toxemia may also be suppressed.

While certain aspects of this alteration of the inflammatory reaction may be beneficial, the suppression of inflammation may mask the signs of infection and tend to facilitate spread of microorganisms. Hence, all patients receiving this drug should be watched for evidence of intercurrent infection. Should infection occur, it must be brought under control by the use of appropriate antibacterial measures, or administration of this preparation

should be discontinued. However, in infections characterized by overwhelming toxicity, methylprednisolone acetate therapy in conjunction with appropriate antibacterial therapy is effective in reducing mortality and morbidity. Without conjoint use of an antibiotic to which the invader-organism is sensitive, injudicious use of the adrenal hormones in animals with infections can be hazardous. As with other corticoids, continued or prolonged use is discouraged.

While no sodium retention or potassium depletion has been observed at the doses recommended, animals receiving methylprednisolone acetate, as with all corticoids, should be under close observation for possible untoward effects. If symptoms of hypopotassemia (hypokalemia) should occur, corticoid therapy should be discontinued and potassium chloride administered by continuous intravenous drip.

Since this drug lacks significant mineralocorticoid activity in usual therapeutic doses, it is not likely to afford adequate support in states of acute adrenocortical insufficiency. For treatment of the latter, the parent adrenocortical steroids, hydrocortisone or cortisone, should be used.

DOSAGE AND ADMINISTRATION

INTRAMUSCULAR

Following intramuscular injection of methylprednisolone acetate, a prolonged systemic effect results. The dose varies with the size of the animal patient, the severity of the condition under treatment, and the animal's response to therapy.

Dogs and Cats

The average intramuscular dose for dogs is 20 mg. In accordance with the size of the dog and severity of the condition under treatment, the dose may range from 2 mg in miniature breeds to 40 mg in medium breeds, and even as high as 120 mg in extremely large breeds or dogs with severe involvement.

The average intramuscular dose for cats is 10 mg with a range up to 20 mg.

Injections may be made at weekly intervals or in accordance with the severity of the condition and clinical response.

Horses

The usual intramuscular dose for horses is 200 mg repeated as necessary.

For maintenance therapy in chronic conditions, initial doses should be reduced gradually until the smallest effective (ie, individualized) dose is established. MEDROL® Tablets containing methylprednisolone may also be used for maintenance in dogs and cats, administered according to the recommended dose.

When treatment is to be withdrawn after prolonged and intensive therapy, the dose should be reduced gradually.

If signs of stress are associated with the condition being treated, the dose should be increased. If a rapid hormonal effect of maximum intensity is required, as in anaphylactic shock, the intravenous administration of highly soluble SOLU-DELTA-CORTEF® Sterile Powder containing prednisolone sodium succinate is indicated.

INTRASYNOVIAL

Methylprednisolone acetate, a slightly soluble ester of methylprednisolone, is capable of producing a more prolonged local anti-inflammatory effect than equimolar doses of hydrocortisone acetate. Following intrasynovial injection, relief from pain may be experienced within 12 to 24 hours. The duration of relief varies, but averages three to four weeks, with a range of one to five or more weeks. Injections of methylprednisolone acetate have been well tolerated. Intrasynovial (intra-articular) injections may occasionally result in an increased localized inflammatory response.

Intrasynovial injection is recommended as an adjuvant to general therapeutic measures to effect suppression of inflammation in one or a few peripheral structures when (1) the disease is limited to one or a few peripheral structures; (2) the disease is widespread with one or a few peripheral structures actively inflamed; (3) systemic therapy with other corticoids or corticotropin controls all but a few of the more actively involved structures; (4) systemic therapy with cortisone, hydrocortisone, or corticotropin is contraindicated; (5) joints show early but actively progressing deformity (to enhance the effect of physiotherapy and corrective procedures); and (6) surgical or other orthopedic corrective measures are to be or have been done.

The action of DEPO-MEDROL injected intrasynovially appears to be well localized since significant metabolic effects characteristic of systemic administration of adrenal steroids have not been observed. In a few instances mild and transient improvement of structures other than those injected have been reported. No other systemic effects have been noted. However, it is possible that mild systemic effects may occur following intrasynovial administration, and this possibility is greater the larger the number of structures injected and the higher the total dose employed.

Procedure for Intrasynovial Injection

The anatomy of the area to be injected should be reviewed in order to assure that the suspension is properly placed and to determine that large blood vessels or nerves are avoided. The injection site is located where the synovial cavity is most superficial. The area is prepared for aseptic injection of the medicament by the removal of hair and cleansing of the skin with alcohol or Mercresin® tincture. A sterile 18- to 21-gauge needle for horses, 20- to 22-gauge needle for dogs, on a dry syringe is quickly inserted into the synovial space and a small amount of synovial fluid withdrawn. If there is an excess of synovia and more than 1 mL of suspension is to be injected, it is well to aspirate a volume of fluid comparable to that which is to be injected. With the needle in place, the aspirating syringe is removed and replaced by a second syringe containing the proper amount of suspension which is then injected. In some animals a transient pain is elicited immediately upon injection into the affected cavity. This pain varies from mild to

severe and may last for a few minutes up to 12 hours. After injection, the structure may be moved gently a few times to aid mixing of the synovial fluid and the suspension. The site may be covered with a small sterile dressing.

Areas not suitable for injection are those that are anatomically inaccessible such as spinal joints and those like the sacroiliac joints, which are devoid of synovial space. Treatment failures are most frequently the result of failure to enter the synovial space. If failures occur when injections into the synovial spaces are certain, as determined by aspiration of fluid, repeated injections are usually futile. Local therapy does not alter the underlying disease process, and whenever possible comprehensive therapy including physiotherapy and orthopedic correction should be employed.

The single intrasynovial dose depends on the size of the part, which corresponds to the size of the animal. The interval between repeated injections depends on the duration of relief obtained.

Horses

The average initial dose for a large synovial space in horses is 120 mg with a range from 40 to 240 mg. Smaller spaces will require a correspondingly lesser dose.

Dogs

The average initial dose for a large synovial space in dogs is 20 mg. Smaller spaces will require a correspondingly lesser dose.

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

Contents should be used within 12 weeks after the first dose is removed.

HOW SUPPLIED

DEPO-MEDROL, 20 mg/mL is available in 20 mL vials, and 40 mg/mL is available in 5 mL vials.

Approved by FDA under NADA # 012-204


zoetis

Distributed by:
Zoetis Inc.
Kalamazoo, MI 49007

Revised: May 2019


50334301

PRINCIPAL DISPLAY PANEL - 20 mg Vial Carton

<p>See package insert for complete product information.</p> <p>Warning—Not for human use. Do not use in horses intended for human consumption.</p> <p>Shake well immediately before each use.</p> <p>Store at controlled room temperature 20° to 25° C (68° to 77° F).</p> <p>Contents should be used within 12 weeks after the first dose is removed.</p> <p>Each mL contains: Methylprednisolone acetate.....20 mg Also Polyethylene glycol 3350 29.6 mg Sodium chloride 8.9 mg Myristyl-gamma-picolinium chloride 0.197 mg added as preservative</p> <p>When necessary, pH was adjusted with sodium hydroxide and/or hydrochloric acid.</p> <p>50374502</p>	<p>20 mL Vial</p> <p>Depo-Medrol® (methylprednisolone acetate injectable suspension)</p> <p>20 mg per mL</p> <p>For Intramuscular or Intrasynovial Use Only</p> <p>For Use in Animals Only</p> <p>Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>Approved by FDA under NADA # 012-204</p> <p>zoetis</p>	<p>20 mL Vial</p> <p>Depo-Medrol® (methylprednisolone acetate injectable suspension)</p> <p>20 mg per mL</p> <p>For Intramuscular or Intrasynovial Use Only</p> <p>For Use in Animals Only</p> <p>Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>Approved by FDA under NADA # 012-204</p> <p>zoetis</p>	<p>FPO: UPC @ 100%</p>  <p>3 0009-0613-04 4</p> <p>Distributed by: Zoetis Inc. Kalamazoo, MI 49007</p> <p>zoetis</p>
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Depo-Medrol 20 mg

PRINCIPAL DISPLAY PANEL - 40 mg Vial Carton

<p>See package insert for complete product information.</p> <p>Warning—Not for human use. Do not use in horses intended for human consumption.</p> <p>Shake well immediately before each use.</p> <p>Store at controlled room temperature 20° to 25° C (68° to 77° F).</p> <p>Contents should be used within 12 weeks after the first dose is removed.</p> <p>Each mL contains: Methylprednisolone acetate.....40 mg Also Polyethylene glycol 3350 29.1 mg Sodium chloride 8.7 mg Myristyl-gamma-picolinium chloride 0.194 mg added as preservative</p> <p>When necessary, pH was adjusted with sodium hydroxide and/or hydrochloric acid.</p> <p>50374402</p>	<p>One 5 mL Vial</p> <p>Depo-Medrol® (methylprednisolone acetate injectable suspension)</p> <p>40 mg per mL</p> <p>For Intramuscular or Intrasynovial Use Only</p> <p>For Use in Animals Only</p> <p>Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>Approved by FDA under NADA # 012-204</p> <p>zoetis</p>	<p>One 5 mL Vial</p> <p>Depo-Medrol® (methylprednisolone acetate injectable suspension)</p> <p>40 mg per mL</p> <p>For Intramuscular or Intrasynovial Use Only</p> <p>For Use in Animals Only</p> <p>Caution: Federal (USA) law restricts this drug to use by or on the order of a licensed veterinarian.</p> <p>Approved by FDA under NADA # 012-204</p> <p>zoetis</p>	<p>FPO: UPC 100%</p>  <p>3 00090161401 0</p> <p>Distributed by: Zoetis Inc. Kalamazoo, MI 49007</p> <p>zoetis</p>
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Depo-Medrol 40 mg

DEPO-MEDROL

methylprednisolone acetate injection, suspension

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-1613
Route of Administration	INTRAMUSCULAR, INTRASYNOVIAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYLPREDNISOLONE ACETATE (UNII: 43502P7F0P) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE ACETATE	20 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	29.6 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-1613-1	20 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA012204	04/15/1960	

DEPO-MEDROL

methylprednisolone acetate injection, suspension

Product Information

Product Type	PRESCRIPTION ANIMAL DRUG	Item Code (Source)	NDC:54771-1614
Route of Administration	INTRAMUSCULAR, INTRASYNOVIAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
METHYLPREDNISOLONE ACETATE (UNII: 43502P7F0P) (METHYLPREDNISOLONE - UNII:X4W7ZR7023)	METHYLPREDNISOLONE ACETATE	40 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	29 mg in 1 mL
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:54771-1614-1	5 mL in 1 VIAL		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NADA	NADA012204	04/15/1960	

Labeler - Zoetis Inc. (828851555)

Revised: 12/2021

Zoetis Inc.