

Pfizer

دپوميڈرول  
Depo-Medrol®

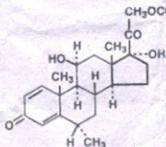
(Methylprednisolone Acetate)  
Sterile Aqueous Suspension

**DESCRIPTION**

Depo-Medrol® is an anti-inflammatory glucocorticoid for intramuscular, intra-articular, soft tissue or intralesional injection. It is available as 40 mg/ml, 80 mg/2 ml.

Each ml of these preparations contains:

Methylprednisolone acetate 40 mg, Polyethylene glycol 3350, Methyl-gamma-butyrolactone chloride, Sodium Chloride, Water for injection q.s. The chemical name for methylprednisolone acetate is pregna-1,4-diene-3,20-dione, 21(acetyloxy)-11,17-dihydroxy-6-methyl-, (6 $\alpha$ ,16 $\beta$ ) and the molecular weight is 416.51.



Depo-Medrol® Sterile Aqueous Suspension contains methylprednisolone acetate which is the 6-methyl derivative of prednisolone. Methylprednisolone acetate is a white or practically white, odorless, crystalline powder which melts at about 215° with some decomposition. It is soluble in dioxane, sparingly soluble in acetone, in alcohol, in chloroform, and in methanol, and slightly soluble in ether. It is practically insoluble in water.

**THERAPEUTIC INDICATIONS**

**A. FOR INTRAMUSCULAR ADMINISTRATION**  
When oral therapy is not feasible and the strength, dosage form, and route of administration of the drug reasonably lend the preparation to the treatment of the condition, the intramuscular use of Depo-Medrol® Sterile Aqueous Suspension (methylprednisolone acetate) is indicated as follows:

- 1. Endocrine Disorders**
  - Primary or secondary adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice; synthetic analogs may be used in conjunction with mineralocorticoids where applicable, in infancy, mineralocorticoid supplementation is of particular importance).
  - Acute adrenocortical insufficiency (hydrocortisone or cortisone is the drug of choice, mineralocorticoid supplementation may be necessary particularly when synthetic analogs are used).
  - Congenital adrenal hyperplasia
  - Adrenocarcinoma associated with cancer
  - Nonsuppurative thyroiditis
- 2. Rheumatic Disorders:** As adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:
  - Post-traumatic osteoarthritis
  - Synovitis of osteoarthritis
  - Epicondylitis
  - Acute nonspecific tenosynovitis
  - Rheumatoid arthritis, including juvenile rheumatoid arthritis (selected cases may require low-dose maintenance therapy)
  - Psoriatic arthritis
  - Acute gouty arthritis
  - Ankylosing spondylitis
  - Acute and subacute bursitis

- 3. Collagen Diseases:** During an exacerbation or as maintenance therapy in selected cases of:
  - Systemic lupus erythematosus
  - Systemic dermatomyositis (polymyositis)
  - Acute rheumatic carditis

**4. Dermatologic Diseases**

- Pemphigus
- Bullous dermatitis
- Severe erythema multiforme herpetiformis (Stevens-Johnson syndrome)
- Severe seborrheic dermatitis
- Exfoliative dermatitis
- Dykess lupoides
- Severe psoriasis

**5. Allergic States:** Control of severe or incapacitating allergic conditions intractable to adequate trials of conventional treatment in:

- Bronchial asthma
- Drug hypersensitivity reactions
- Urticarial transfusion reactions
- Contact dermatitis
- Atopic dermatitis
- Serum sickness
- Seasonal or perennial allergic rhinitis
- Acute noninfectious laryngeal edema (epinephrine is the drug of first choice)

**6. Ophthalmic Diseases:** Severe acute and chronic allergic and inflammatory processes involving the eye, such as:

- Herpes zoster ophthalmicus
- Drug hypersensitivity reactions
- Iritis, iridocyclitis
- Anterior segment inflammation
- Chorioretinitis
- Allergic conjunctivitis
- Diffuse posterior uveitis
- Allergic corneal marginal ulcers
- Ocular neuritis
- Keratitis

**7. Gastrointestinal Diseases:** To tide the patient over a

critical period of the disease in:

- Ulcerative colitis (systemic therapy)
  - Regional enteritis (systemic therapy)
- 8. Respiratory Diseases**
    - Flamingo or disseminated pulmonary tuberculosis when used concurrently with appropriate anti-tuberculous chemotherapy
    - Symptomatic sarcoidosis
    - Berlyiosis
    - Loeffler's syndrome not manageable by other means
    - Aspiration pneumonitis
  - 9. Hematologic Disorders**
    - Acquired (autonomous) hemolytic anemia
    - Erythroblastopenia (RBC anemia)
    - Appropriate anti-tuberculous chemotherapy in adults
    - Congenital (erythroid) hypoplastic anemia

**10. Neoplastic Diseases:** For palliative management of:

- Leukemias and lymphomas
- Acute leukemia of childhood

**11. Edematous States:** To induce diuresis or remission of proteinuria in the nephrotic syndrome, without, uremia, of the idiopathic type or that due to lupus erythematosus.

- 12. Nervous System**
- 13. Acute exacerbations of multiple sclerosis.**

**14. Miscellaneous**

- Tuberculous meningitis with subarachnoid block or impending block when used concurrently with appropriate anti-tuberculous chemotherapy.
- Trichinosis with neurologic or myocardial involvement.

**B. FOR INTRA-SYNOVIAL OR SOFT TISSUE ADMINISTRATION (including periarticular and intrabursal -SEE WARNINGS)**

Depo-Medrol® is indicated as adjunctive therapy for short-term administration (to tide the patient over an acute episode or exacerbation) in:

- Synovitis of osteoarthritis
- Epicondylitis
- Rheumatoid arthritis
- Acute nonspecific tenosynovitis
- Acute and subacute bursitis
- Post-traumatic osteoarthritis
- Acute gouty arthritis

**C. FOR INTRALESIONAL ADMINISTRATION**

Depo-Medrol® is indicated for intralesional use in the following conditions:

- Keloids, Localized hypertrophic, infiltrated, inflammatory lesions of:
- Lichen planus, psoriatic plaques
- Discoid lupus erythematosus
- Necrobiosis lipoidica diabetorum
- Granuloma annulare
- Lichen simplex chronicus (neurodermatitis)
- Alopecia areata

Depo-Medrol® may also be useful in cystic tumors or an spontaneous or tendon (ganglion).

**D. FOR INTRACUTANEOUS INSTALLATION**

- Ulcerative colitis

**POSOLOGY AND METHOD OF ADMINISTRATION**

**Because of possible physical incompatibilities, Depo-Medrol® Sterile Aqueous Suspension (methylprednisolone acetate) should not be diluted or mixed with other solutions.** Parenteral suspensions should be inspected visually for any foreign particulate matter and discoloration prior to administration whenever drug product and container permit.

**Administration for Local Effect:** Therapy with Depo-Medrol® does not obviate the need for the usual systemic therapy usually employed. Although such a method of treatment will ameliorate symptoms, it is in no sense a cure and the hormone has no effect on the cause of the inflammation.

- 1. Rheumatoid and Osteoarthritis:** The dose for intra-articular administration depends upon the size of the joint and varies with the severity of the condition in the individual patient. Chronic cases, if necessary, may be repeated at intervals ranging from one to five or more weeks depending upon the degree of relief obtained from the initial injection.

The doses in the following table are given as a general guide:

Size of Joint	Examples	Range of Dosage
Large	Knees	20-80 mg
	Ankles	
	Shoulders	
Medium	Elbows	10-40 mg
	Wrists	
Small	Metacarpophalangeal Interphalangeal Sternoclavicular Acromioclavicular	4-10 mg

**Procedure:** It is recommended that the anatomy of the joint involved be reviewed before attempting intra-articular injection. In order to obtain the full anti-inflammatory effect, it is important that the injection be made into the synovial space. The same injection technique as for a lumbar puncture, a sterile 20 to 24 gauge needle (on a dry syringe) is quickly inserted into the synovial cavity. Procaine infiltration is elective. The aspiration of only a few drops of joint fluid proves the joint space has been entered by the needle. The injection site for each joint is determined by that location which contains the most superficial and most free of large vessels and nerves. With the needle in place, the aspirating syringe is removed and replaced by a second syringe containing the desired amount of Depo-Medrol®. The plunger is then pushed outward slightly to aspirate synovial fluid and to make sure the needle is still in the synovial space. After injection, the joint is moved gently a few times to aid mixing of the synovial fluid and the suspension. The site is covered with a small sterile dressing. Suitable sites for intra-articular injection are the knee, ankle, elbow, shoulder, phalangeal, and hip joints. Since diffusion is occasionally encountered in entering the hip joint, precautions

should be taken to avoid any large blood vessels in the area. Joints not suitable for injection are those that are anatomically inaccessible, such as the spinal joints and those that the sacroiliac joints that are devoid of synovial space. Treatment failures are most frequently the result of failure to enter the joint space. Little or no benefit follows injection into soft tissue. If a fallujra occurs 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. Following intra-articular corticosteroid therapy, care should be taken to avoid overuse of joints in which symptomatic benefit has been obtained. Following injection into soft tissue, an increase in joint deterioration that will more than offset the beneficial effects of the steroid.

Unstable joints should not be injected. Repetitive intra-articular injection may in some cases result in instability of the joint. X-ray follow-up is suggested in selected cases to detect deterioration.

If a local anesthetic is used prior to injection of Depo-Medrol®, the anesthetic package insert should be read carefully and all the precautions observed.

- 2. Bursitis:** The area around the injection site is prepared in a sterile way and a wheel at the site made with 1 percent procaine hydrochloride solution. A 20 to 24 gauge needle attached to a dry syringe is inserted into the bursal space. The aspirating syringe is held in place and the aspirating syringe emptied by a small syringe containing the desired dose. After injection, the needle is withdrawn and a small dressing applied.

- 3. Miscellaneous: Ganglion, Tendinitis, Epicondylitis:** In the treatment of conditions such as tendinitis or tenosynovitis, the needle should be inserted into the bursal space of a bursa adjacent to the overlying skin, to inject the suspension into the tendon sheath rather than into the substance of the tendon. The tendon may be held in place when the patient is in a stretch. When treating conditions such as epicondylitis, the area of greatest tenderness should be outlined carefully and the suspension infiltrated into the area. For epicondylitis of the elbow, the suspension is injected directly into the cyst. In many cases, the suspension may cause a marked decrease in the size of the cystic tumor and may effect disappearance. The usual safety precautions should be observed, of course, with each injection.

The dose in the treatment of the various conditions of the tendinitis or bursal structure should be read carefully with the condition being treated and ranges from 4 to 30 mg. In recurrent or chronic conditions, repeated injections may be necessary.

**4. Injections for Local Effect in Dermatologic Conditions.**

Following cleansing with an appropriate antiseptic such as 70% alcohol, 20 to 60 mg of the suspension is injected into the lesion. It may be repeated at intervals ranging from 10 to 20 to 40 mg by repeated local injections in the case of large lesions. Care should be taken to avoid injection of sufficient quantity of the suspension to cause a marked decrease in the size of a small lesion. One to four injections are usually employed; the intervals between injections varying with the type of lesion being treated and the duration of improvement produced by the initial injection.

The following statement refers to the benzyl alcohol formulation only:

When multidose vials are used, special care to prevent contamination of the contents is essential (see WARNINGS).

**Administration for Systemic Effect**

The intramuscular dosage will vary with the condition being treated. When a prolonged effect is desired, the weekly dose may be maintained by multiple intramuscular doses of 7 and 7 given as a single intramuscular injection.

Dosage must be individualized according to the severity of the disease and response of the patient. For infants and children, the recommended dosage will have to be reduced, but dosage should be governed by the severity of the condition rather than by strict adherence to the table indicated for age or body weight.

Hormone therapy is adjunct to, and not a replacement for, other therapy. Drug dosage must be decreased or discontinued gradually when the drug has been administered for more than a few days. The severity, prognosis and expected duration of the disease and the reaction of the patient to the medication are primary factors in determining dosage. If a period of spontaneous remission occurs in a chronic condition, treatment should be discontinued. Routine laboratory studies, such as analysis, venous postprandial blood sugar, determination of blood pressure and body weight, and a chest x-ray should be made at regular intervals during prolonged therapy. Upper GI x-rays are desirable in patients with an ulcer history or significant dyspepsia.

In patients with the **adrenogenital syndrome**, a single intramuscular injection of 40 mg every two weeks may be adequate. For maintenance of patients with rheumatoid arthritis, the weekly intramuscular dose will vary from 40 to 120 mg. The usual dosage for patients with dermatologic lesions benefited by systemic corticoid therapy is 40 to 120 mg of methylprednisolone acetate administered intramuscularly every 7 to 10 days. In acute severe dermatitis due to poison ivy, relief may result within 10 to 12 hours following intramuscular administration of a single dose of 80 to 120 mg in chronic cases. In severe dermatitis, repeated injections at 5 to 10 day intervals may be necessary. In seborrheic dermatitis, a weekly dose of 80 mg may be adequate to control the condition.

Following IM administration of 80 to 120 mg to asthmatic patients, relief may result within 6 to 48 hours and persist for several days to two weeks. Similar relief may be obtained in patients with an intramuscular dose of 80 to 120 mg who have been administered oral therapy. Relief may be followed by relief of corneal symptoms within six hours persisting for several days to three weeks.

In signs and symptoms associated with the condition being treated, the dosage of the suspension should be increased. If a rapid hormonal effect of maximum intensity is required, the intravenous administration of highly soluble methylprednisolone sodium succinate is indicated.

