injury initial doses of the equivalent of up to 30 mg/kg of methylprednisolone have been given by bolus intravenous injection over 15 minutes and followed, after a 45-minute pause, by intravenous infusion of 5.4 mg/kg per hour over 24 hours or longer. For slow intravenous infusion methylprednisolone sodium succinate is dissolved in an appropriate volume of glucose 5% or sodium chloride 0.9%.
Parenteral doses in children have varied considerably, depending on the condition: a range of 1 to 30 mg/kg of methylprednisolone daily has been given by the intravenous or intramuscular routes. A total dose of 1 g daily should not normally be exceeded.

OVERDOSAGE

Treatment of acute overdosage is by supportive and symptomatic therapy. For chronic overdosage in the face of severe disease requiring continuous steroid therapy, the dosage of the corticosteroid may be reduced only temporarily, or alternate day treatment may be introduced.

NURSING MOTHERS

Systemically administered corticosteroids appear in human milk and could suppress growth, interfere with endogenous corticosteroid production, or cause other untoward effects. Because of the potential for serious adverse reactions in nursing infants from corticosteroids, a decision should be made whether to continue nursing, or discontinue the drug, taking into account the importance of the drug to the mother.

PREGNANCY CATEGORY C.

Corticosteroids have been shown to be teratogenic in many species when given in doses equivalent to the human dose. Animal studies in which corticosteroids have been given to pregnant mice, rats, and rabbits have yielded an increased incidence of cleft palate in the offspring. There are no adequate and well-controlled studies in pregnant women. Corticosteroids should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Infants born to mothers who have received corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

ADVERSE REACTIONS

The following adverse reactions have been reported with methylprednisolone sodium succinate or other corticosteroids:

Allergic reactions: Allergic or hypersensitivity reactions, anaphylactoid reaction, anaphylaxis, angioedema.

Blood and lymphatic system disorders: Leukocytosis.

Cardiovascular: Bradycardia, cardiac arrest, cardiac arrhythmias, cardiac enlargement, circulatory collapse, congestive heart failure, fat embolism, hypertension, hypertrophic cardiomyopathy in premature infants, myocardial rupture following recent myocardial infarction, pulmonary edema, syncope, tachycardia, thromboembolism, thrombophlebitis, vasculitis.

Dermatologic: Acne, allergic dermatitis, burning or tingling (especially in the perineal area after intravenous injection), cutaneous and subcutaneous atrophy, dry scaly skin, ecchymoses and petechiae, edema, erythema, hyperpigmentation, hypopigmentation, impaired wound healing, increased sweating, rash, sterile abscess, striae, suppressed reactions to skin tests, thin fragile skin, thinning scalp hair, urticaria.

Endocrine: Decreased carbohydrate and glucose tolerance, development of cushingoid state, glycosuria, hirsutism, hypertrichosis, increased requirements for insulin or oral hypoglycemic agents in diabetes, manifestations of latent diabetes mellitus, menstrual irregularities, secondary adrenocortical and pituitary unresponsiveness (particularly in times of stress, as in trauma, surgery, or illness), suppression of growth in pediatric patients.

Fluid and electrolyte disturbances: Congestive heart failure in susceptible patients, fluid retention, hypokalemic alkalosis, potassium loss, sodium retention.

Gastrointestinal: Abdominal distention, bowel/bladder dysfunction (after intrathecal administration), elevation in serum liver enzyme levels (usually reversible upon discontinuation), hepatomegaly, increased appetite, nausea, pancreatitis, peptic ulcer with possible perforation and hemorrhage, perforation of the small and large intestine (particularly in patients with inflammatory bowel disease), ulcerative esophagitis.

Hepatobiliary: Hepatitis

Metabolic: Negative nitrogen balance due to protein catabolism.

Musculoskeletal: Aseptic necrosis of femoral and humer
al heads, Charcot-like arthropathy, loss of muscle mass, muscle weakness, osteoporosis, pathologic fracture of long bones, postinjection flare (following intra-articular use), steroid myopathy, tendon rupture, vertebral compression fractures.

Other: Abnormal fat deposits, decreased resistance to infection, hiccups, increased or decreased motility and number of spermatozoa, injection site infections following non-sterile administration, malaise, moon face, weight gain.

Storage: - Store below 25°C till reconstitution. Protect from light & moisture.

Improper Storage may deteriorate the product

Keep the medicine out of reach of children.

Presentation: - Each pack contain 1000mg / 500 mg 125 mg / 40 mg of methylprednisolone sodium succinate USP Injection in a vial.

Manufactured by:

AMERICAN REMEDIES
Care & Cure with Research
American Remedies Healthcare Pvt. Ltd.
(An ISO 9001-2015 Certified Company)

ICO: American Remedies LLC, DE, USA
Gala No. 105 to 111, 1st Flr., Bldg. No. E-15/A, Harihar Complex, Bhiwandi, Mumbai - 421302
At: Vill. Surajpur Nahan Road Paonta Sahib, Distt. Sirmour, Himachal Pradesh-173001
E-mail: info@americanremedies.in

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For the use only of a Registered Medical Practitioner of a Hospital or a Laboratory

℞ Methylprednisolone Sodium Succinate for Injection USP

Medrocan

Injection

For I.M./I.V. use only

Composition:-

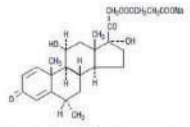
Each vial Contains:-

Sterile Methylprednisolone Sodium Succinate USP
Eq. to Anhydrous Methylprednisolone 40 mg / 125 mg / 500 mg / 1000 mg

Description

Methylprednisolone sodium succinate for injection USP is an anti-inflammatory glucocorticoid, which contains methylprednisolone sodium succinate as the active ingredient. Methylprednisolone sodium succinate USP is the sodium succinate ester of methylprednisolone, and it occurs as a white, or nearly white, odorless hygroscopic, amorphous solid. It is very soluble in water and in alcohol; it is insoluble in chloroform and is very slightly soluble in acetone.

The chemical name for methylprednisolone sodium succinate is pregna-1, 4-diene-3, 20-dione, 21-(3-carboxy-1-oxopropoxy)-11, 17-dihydroxy-6-methyl-monosodium salt, (6α, 11β) - 11β, 17, 21 – Trihydroxy-6α-methylpregna-1, 4-diene-3, 20-di-one 21-(sodium Succinate) and the molecular weight is 496.53. The structural formula is represented below:



Methylprednisolone Sodium Succinate

Methylprednisolone sodium succinate USP is soluble in water; it may be administered in a small volume of diluent and is well suited for intravenous use in situations where high blood levels of methylprednisolone are required rapidly.

CLINICAL PHARMACOLOGY

Glucocorticoids, naturally occurring and synthetic are adrenocortical steroids that are readily absorbed from the gastrointestinal tract.

Naturally occurring glucocorticoids (hydrocortisone and cortisone), which also have salt-retaining properties, are used as replacement therapy in adrenocortical deficiency states. Their synthetic analogs are primarily used for their potent anti-inflammatory effects in disorders of many organ systems. Glucocorticoids cause profound and varied metabolic effects. In addition, they modify the body's immune responses to diverse stimuli.

Methylprednisolone is a potent anti-inflammatory steroid with greater anti-inflammatory potency than prednisolone and even less tendency than prednisolone to induce sodium and water retention.

Methylprednisolone sodium succinate has the same metabolic and anti-inflammatory actions as methylprednisolone. When given parenterally and in equimolar quantities, the two compounds are equivalent in biologic activity. Following the intravenous injection of methylprednisolone sodium succinate, demonstrable effects are evident within one hour and persist for a variable period. Excretion of the administered dose is nearly complete within 12 hours. Thus, if constantly high blood levels are required, injections should be made every 4 to 6 hours. This preparation is also rapidly absorbed when administered intramuscularly and is excreted in a pattern similar to that observed after intravenous injection.

PHARMACOLOGY

For a brief outline of the pharmacokinetics of corticosteroids,

Methylprednisolone is fairly rapidly distributed after oral doses, with a plasma half-life of 3.5 hours or more.

The tissue half-life is reported to range from 18 to 36 hours. Methylprednisolone acetate is absorbed from joints over a week but is more slowly absorbed following deep intramuscular injection. The sodium succinate ester is rapidly absorbed after intramuscular doses, with peak plasma concentrations obtained in 2 hours. Methylprednisolone crosses the placenta.

DOSAGE AND ADMINISTRATION

Methylprednisolone is a corticosteroid with mainly glucocorticoid activity; 4 mg of methylprednisolone is equivalent in anti-inflammatory activity to about 5 mg of prednisolone. It is used, either in the form of the free alcohol or in one of the esterified forms, in the treatment of conditions for which corticosteroid therapy is indicated. Except adrenocortical-deficiency states, for which hydrocortisone with supplementary fludrocortisone is preferred.

When given orally, methylprednisolone usually has an initial dosage range of 4 to 48 mg daily but higher initial doses of up to 100 mg or more daily may be used in acute severe disease.

For parenteral use in intensive or emergency therapy, methylprednisolone sodium succinate may be given by intramuscular or intravenous injection or by intravenous infusion. The intravenous route is preferred for its more rapid effect in emergency therapy. The usual initial intramuscular or intravenous dose ranges from the equivalent of 10 to 500 mg of methylprednisolone daily. Large intravenous doses (over 250 mg) should normally be given slowly over at least 30 minutes; doses up to 250 mg should be given over at least 5 minutes. High doses should generally not be given for prolonged periods; emergency treatment should only be used until the patient is stabilised. High doses given intermittently for a limited period have sometimes been known as 'pulse therapy' (see Administration, below) and in graft rejection up to 1 g has been given daily for up to 3 days. In intensive therapy of acute spinal cord