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

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Methylprednisolone Sodium Succinate for Injection USP 40mg

PREDNIZON-40

Injection

COMPOSITION:
Each vial contains:
Methylprednisolone Sodium Succinate USP
Equivalent to Methylprednisolone 40 mg

DESCRIPTION:
MPSS Sterile Powder 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), and the molecular weight is 496.53
40 mg Single-Dose Vial - Each 1 mL (when reconstituted with 1.2 mL bacteriostatic water for injection with benzyl alcohol) contains methylprednisolone sodium succinate equivalent to 40 mg methylprednisolone; also 1.6 mg monobasic sodium phosphate anhydrous; 17.46 mg dibasic sodium phosphate dried; 25 mg lactose hydrous; 8.8 mg benzyl alcohol added as preservative.

IMPORTANT - Use only Bacteriostatic Water for Injection with Benzyl Alcohol when reconstituting Methylprednisolone Sodium Succinate for Injection, USP. Use within 48 hours after mixing.

CLINICAL PHARMACOLOGY:
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. The relative potency of methylprednisolone and hydrocortisone sodium succinate, as indicated by depression of eosinophil count, following intravenous administration, is at least four to one. This is in good agreement with the relative oral potency of methylprednisolone and hydrocortisone.

INDICATION:
Methylprednisolone may be used locally or systemically, particularly where oral therapy is not feasible. Methylprednisolone may be used by any of the following routes: intramuscular, intra-articular, periarticular, intrabursal, intralesional or into the tendon sheath. It must not be used by the intrathecal or intravenous routes (see Contra-indications and Undesirable effects).

Intramuscular administration:
1. Rheumatic disorders
   Rheumatoid arthritis
2. Collagen diseases/arteritis
   Systemic lupus erythematosus
3. Dermatological diseases
   Severe erythema multiforme (Stevens-Johnson syndrome)
4. Allergic states
   Bronchial asthma
   Severe seasonal and perennial allergic rhinitis
   Drug hypersensitivity reactions
   Angioneurotic oedema
5. Gastro-intestinal diseases
   Ulcerative colitis
   Crohn's disease
6. Respiratory diseases
   Fulminating or disseminated tuberculosis (with appropriate antituberculous chemotherapy)
   Aspiration of gastric contents
7. Miscellaneous
   TB meningitis (with appropriate antituberculous chemotherapy)
   Intra-articular administration:
   Rheumatoid arthritis
   Osteo-arthritis with an inflammatory component
   Soft tissue administration (intrabursal, periarticular, into tendon sheath):
   Synovitis not associated with infection
   Epicondylitis
   Tenosynovitis
   Plantar fasciitis
   Bursitis
   Intralesional:
   Keloids
   Localized lichen planus
   Localized lichen simplex
   Granuloma annulare
   Discoid lupus erythematosus
   Alopecia areata

DOSAGE AND ADMINISTRATION:
When high dose therapy is desired, the recommended dose of methylprednisolone sodium succinate for injection is 30 mg/kg administered intravenously over at least 30 minutes. This dose may be repeated every 4 to 6 hours for 48 hours. In general, high dose corticosteroid therapy should be continued only until the patient's condition has stabilized; usually not beyond 48 to 72 hours. Although adverse effects associated with high dose short-term corticoid therapy are uncommon, peptic ulceration may occur. Prophylactic antacid therapy may be indicated. In other indications initial dosage will vary from 10 to 40 mg of methylprednisolone sodium succinate for injection depending on the clinical problem being treated. The larger doses may be required for short-term management of severe, acute conditions. The initial dose usually should be given intravenously over a period of several minutes. Subsequent doses may be given intravenously or intramuscularly at intervals dictated by the patient's response and clinical condition. Corticoid therapy is an adjunct to, and not replacement for conventional therapy.

Dosage may be reduced for infants and children but should be governed more by the severity of the condition and response of the patient than by age or size. It should not be less than 0.5 mg per kg every 24 hours. Dosage must be decreased or discontinued gradually when the drug has been administered for more than a few days. If a period of spontaneous remission occurs in a chronic condition, treatment should be discontinued. Routine laboratory studies, such as urinalysis, two-hour 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. Methylprednisolone sodium succinate for injection may be administered by intravenous or intramuscular injection or by intravenous infusion, the preferred method for initial emergency use being intravenous injection. To administer by intravenous (or intramuscular) injection, reconstitute the product as follows:

Each vial of Methylprednisolone Sodium Succinate for Injection USP 40 mg is reconstitution with 1.2 ml of Sterile Water for Injection IP. Each vial of Methylprednisolone Sodium Succinate for Injection USP 125 mg is reconstitution with 2.1 ml of Sterile Water for Injection IP. Each vial of Methylprednisolone Sodium Succinate for Injection USP 500 mg is reconstitution with 5 ml of Sterile Water for Injection IP for I.M use in 10ml for I.V use. Each vial of Methylprednisolone Sodium Succinate for Injection USP 1000 mg is reconstitution with 8 ml of Sterile Water for Injection IP I.M use in 16mL for I.V. use. To prepare solutions for intravenous infusion, first prepare the solution for injection as directed. This solution may then be added to indicated amounts of 5% dextrose in water, isotonic saline solution or 5% dextrose in water isotonic saline solution or 5% dextrose in isotonic saline solution.

CONTRAINDICATION:
Methylprednisolone is contra-indicated where there is known hypersensitivity to components and in systemic infection unless specific anti-infective therapy is employed. Due to its potential for neurotoxicity, Methylprednisolone must not be given by the intrathecal route. In addition, as the product is a suspension it must not be given by the intravenous route (see Undesirable effects).

WARNING:
In patients on corticosteroid therapy subjected to any unusual stress, increased dosage of rapidly acting corticosteroids before, during, and after the stressful situation is indicated. Corticosteroids may mask some signs of infection, and new infections may appear during their use. There may be decreased resistance and inability to localize infection when corticosteroids are used. Usage in pregnancy. Since adequate human reproduction studies have not been done with corticosteroids, the use of these drugs in pregnancy, nursing mothers, or women of childbearing potential requires that the possible benefits of the drug be weighed against the potential hazards to the mother and embryo or fetus. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hypoadrenalism.

PRECAUTIONS:
General
Drug-induced secondary adrenocortical insufficiency may be minimized by gradual reduction of dosage. This type of relative insufficiency may persist for months after discontinuation of therapy; therefore, in any situation of stress occurring during that period, hormone therapy should be reinstituted. Since mineralocorticoid secretion may be impaired, salt and/or a mineralocorticoid should be administered concurrently. There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis. Corticosteroids should be used cautiously in patients with ocular herpes simplex because of possible corneal perforation. The lowest possible dose of corticosteroid should be used to control the condition under treatment, and when reduction in dosage is possible, the reduction should be gradual.

Psychic derangements may appear when corticosteroids are used, ranging from euphoria, insomnia, mood swings, personality changes, and severe depression, to frank psychotic manifestations. Also, existing emotional instability or psychotic tendencies may be aggravated by corticosteroids. Aspirin should be used cautiously in conjunction with corticosteroids in hypoprothrombinemia. Steroids should be used with caution in nonspecific ulcerative colitis, if there is a probability of impending perforation, abscess or other pyogenic infection; diverticulitis; fresh intestinal anastomoses; active or latent peptic ulcer; renal insufficiency; hypertension; osteoporosis; and myasthenia gravis. Growth and development of infants and children on prolonged corticosteroid therapy should be carefully observed. Although controlled clinical trials have shown corticosteroids to be effective in speeding the resolution of acute exacerbations of multiple sclerosis, they do not show that corticosteroids affect the ultimate outcome or natural history of the disease. The studies do show that relatively high doses of corticosteroids are necessary to demonstrate a significant effect (See DOSAGE AND ADMINISTRATION). Since complications of treatment with glucocorticoids are dependent on the size of the dose and the duration of treatment, a risk/benefit decision must be made in each individual case as to dose and duration of treatment and as to whether daily or intermittent therapy should be used.

Interactions
Drug interactions
The pharmacokinetic interactions listed below are potentially clinically important. Mutual inhibition of metabolism occurs with concurrent use of cyclosporine and methylprednisolone; therefore, it is possible that adverse events associated with the individual use of either drug may be more apt to occur. Convulsions have been reported with concurrent use of methylprednisolone and cyclosporine.

Information for patients
Persons who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chicken pox or measles. Patients should also be advised that if they are exposed, medical advice should be sought without delay.

ADVERSE REACTION:
Fluid and Electrolyte Disturbances
Musculoskeletal
Gastrointestinal
Dermatologic
Neurological
Endocrine
Ophthalmic
Metabolic

STORAGE: Store at a temperature not exceeding 25°C. Protect from moisture.

SHELF LIFE :
24 month.

PRESENTATION:
One vial with Water for Injection IP in a carton along with pack insert.

Manufactured by :
Protech Telelinks
(A WHO-GMP Certified Co.)
Mauza Ogli, Suketi Road, Kala Amb,
Distt Sirmaur (H.P.)

windlas

Marketed by :
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