**INDICATIONS AND USAGE:**

Dexamethasone sodium phosphate injection is indicated for the oral, parenteral, or intramuscular administration for the treatment of a variety of inflammatory and edematous disorders, including those involving the adrenocortical deficiency states. Their synthetic glucocorticoid activity is primarily manifested in the tissues through the action of corticosteroid receptors and the subsequent inhibition of the local synthesis of inflammatory mediators. These agents are particularly useful in the suppression of true inflammatory and edematous processes, of acute and chronic allergic conditions, and of acute rheumatic episodes, that are mediated through the participation of prostaglandins, leukotrienes, and other mediators of inflammation. Some of these agents are also effective in the treatment and control of many of the manifestations of asthma and other allergic conditions, especially those associated with bronchial hyperreactivity.

**Rheumatic Disorders**

Ankylosing spondylitis

Acute gouty arthritis

Synovitis of osteoarthritis

**Ophthalmic Diseases**

Allergic conjunctivitis

Optic neuritis

**Respiratory Diseases**

Bronchial asthma

**Gastrointestinal Diseases**

Regional enteritis (Systemic therapy)

Ulcerative colitis (Systemic therapy)

**Allergic States**

Atopic dermatitis

Seasonal or perennial allergic rhinitis

Serum sickness

**Other**

Rheumatoid arthritis

Severe seborrheic dermatitis

Exfoliative dermatitis

**ADVERSE REACTIONS:**

The use of dexamethasone sodium phosphate may produce systemic adverse reactions which may be of varying severity depending upon the dosage used, the duration of therapy, and the site of injection. These reactions may range from short-lived adverse reactions such as skin redness and warmth, to reversible conditions such as hypokalemia, to irreversible conditions such as growth suppression in children, and may be life-threatening (see WARNINGS).

**Cardiovascular:**

Arrhythmia

Exophthalmos

Glaucoma

Posterior subcapsular cataracts

**Metabolic:**

Hypokalemic alkalosis

Fluid retention

**Musculoskeletal:**

Joint disease, arthritis, osteoporosis

**Neurological:**

Tendon rupture

**Ophthalmic:**

Suppression of normal ocular response to adrenergic stimuli

**Systemic fungal infections (see also WARNINGS) with respect to antifungal therapy.**

**Allergic reactions:**

Drug reactions due to amphotericin B.

**Sensitivity:**

Patients with a history of sensitivity to amphotericin B should be treated with caution; cross-sensitivity between amphotericin B and dexamethasone may exist.

**Hypersensitivity:**

Intravenous or direct intramuscular injection has caused anaphylactoid reactions, urticaria, angioneurotic edema, fever, chills, generalized skin reactions, and in some cases, hypotension. The possibility of sensitivity reactions occurring with intravenous or direct intramuscular injection should be kept in mind when planning to use dexamethasone sodium phosphate injection. These patients should be observed closely during and for a period after discontinuation of the drug. The slower rate of absorption by intramuscular injection is not sufficient to prevent serious local reactions, therefore, the intravenous route of administration should be used when indicated. In cases of anaphylactoid reactions, treatment should be symptomatic and supportive. When it is suspected that an adverse reaction to dexamethasone sodium phosphate injection occurred, the product should be discontinued and appropriate therapy should be instituted.

**Pregnancy:**

Animal reproduction studies have not been conducted with this drug. It is not known whether dexamethasone sodium phosphate injection will affect the fetal plasma concentrations of cortisol or other metabolic processes. Oral administration of dexamethasone to pregnant rats at 10 times the daily human dose did not increase the incidence of congenital anomalies. Dexamethasone sodium phosphate is not a substitute for corticosteroids when the adrenal cortical function is impaired. In early pregnancy, dexamethasone sodium phosphate injection should be used with caution. When corticosteroids are necessary during the latter trimester, they should be used with caution and at the lowest effective dose to minimize adverse effects in the newborn infant. When adrenocortical insufficiency is present, antecedent therapy with a glucocorticoid is indicated. The infusion of a glucocorticoid or physiological saline solution is recommended. When corticosteroids are necessary during the latter trimester of pregnancy, dexamethasone sodium phosphate injection should be used to treat the pregnant woman in those situations in which the potential benefits of the drug to the mother outweigh the possible risks to the fetus. Dexamethasone sodium phosphate injection has been used in patients with mild to moderate adrenocortical insufficiency during labor. Although no fetal adrenal suppression was noted in the case reports, the possible interference with the child's adrenocortical function is of concern.

**Lactation:**

Although no controlled studies have been conducted to determine whether dexamethasone sodium phosphate injection is secreted in human milk, it is not known whether it is present in breast milk. Because many drugs are excreted in human milk, caution should be exercised when a glucocorticoid is administered to a nursing mother.

**PEDIATRIC USE:**

Safety and efficacy in children have not been established.

**GERIATRIC USE:**

Geriatric patients are at increased risk of developing Cushing’s syndrome and should be monitored closely. The dosage requirements may be reduced in elderly patients due to age-related decreased corticosteroid clearance and the potential for adverse reactions.

**ADVERSE REACTIONS:**

**Allergic Reactions:**

Anaphylactoid reactions, urticaria, angioneurotic edema, fever, chills, generalized skin reactions, and in some cases, hypotension.

**Respiratory:**

Bronchospasm, wheezing, and dyspnea.

**Gastrointestinal:**

Nausea, vomiting, cramps, and diarrhea.

**Genitourinary:**

Increased urinary output and urgency in the elderly.

**Musculoskeletal:**

Joint disease, arthritis, pseudoparalysis.

**Neurological:**

Nervousness, excitability, convulsions, coma.

**Ophthalmic:**

Exophthalmos, conjunctivitis, anterior segment inflammation, optic neuritis.

**Skin:**

Redness, rashes, and pruritus.

**Miscellaneous:**

Weight gain, acne, edema, hirsutism.

**Fluid and electrolyte disturbances:**

Hypokalemia and hyperkalemia, hypocalcemia, hypomagnesia, and hypophosphatemia.

**Drug Interactions:**

The use of dexamethasone sodium phosphate in patients receiving anticoagulant therapy may result in increased anticoagulant effects. In such cases, the anticoagulant therapy should be monitored closely and the anticoagulant dosage adjusted accordingly. Some patients on anticoagulant therapy who have been maintained on a stable dosage for several months may experience changes in their anticoagulant requirements when steroid therapy is initiated.

**Infections:**

The use of dexamethasone sodium phosphate injection in patients with osteomyelitis or septicemia may result in septicemia with gram-negative or gram-positive organisms.

**Indications and Usage:**

Dexamethasone sodium phosphate injection is indicated for the treatment of rheumatic disorders, dermatological disorders, inflammatory and edematous conditions, and as an adjuvant in the treatment of certain neoplasms. The drug may be used by the oral, parenteral, or intramuscular routes of administration for the treatment of rheumatic disorders and inflammatory and edematous conditions.

**Neoplasms:**

Carcinoid tumors.

**Further information:**

For complete prescribing information, please see the respective package inserts.
intravenous therapy around the face and head due to hyperglycemia or hyperpigmentation.

Subcutaneous and dermal swelling:

Sterile abscesses:

Pustules and boils (following intra-articular use):

OVERDOSAGE:

Reports of sudden toxicity and/or death following overdose of dexamethasone are rare in the event of overdose, no specific antidote is available. Treatment is supportive and symptomatic.

The rat L.D. of dexamethasone is inhaled mice is 5.2 mg. In animals, inhaled doses of 1 to 2 mg/kg of body weight, intramuscularly, do not appear to be effective. In humans, inhaled doses of 0.3 mg/kg of body weight per 24 hours should be used for maintenance therapy in chronic cases.

Acute Allergic Reactions:

In acute, well-defined allergic disorders or acute exacerbations of chronic allergic disorders, the following dosage schedule combining parenteral and oral therapy is recommended:

1. Intravenous administration of 20 mg of dexamethasone sodium phosphate injection, 0.5 mg per mL, in 200 mL of a suitable infused solution followed by an initial intravenous dose of 4 mg every 4 to 6 hours while shock persists, followed by 4 mg intravenously every 4 to 6 hours while shock persists.

2. Intravenous administration of 10 mg initially followed by repeat intravenous doses of 1 mg every 4 to 6 hours while shock persists.

3. Intravenous administration of 3 mg/kg of body weight per 24 hours as a single intravenous injection.

Administration of high dose corticosteroid therapy should be continued until the patient’s condition has stabilized and usually not longer than 48 to 72 hours.

For adult and pediatric patients who are on corticosteroids, the necessary dose can be determined by the dose given prior to the development of the systemic symptoms.

Reversal of intravenous therapy is usually noted within 1 to 2 hours and recovery may be gradual. In patients with diseases that are resistant to glucocorticoids, the response may be delayed. For patients with refractory shock, the initial dose may be increased to 30 mg per mL every 4 to 6 hours while shock persists.

Patient care should be continued by a physician who has been notified of the administration of high dose prednisone.

When it is mixed with an infusion solution, sterile preparations should be used. Solution should be prepared as needed. Since absorption may be delayed by intramuscular administration, injections should be given at least 10 minutes after the administration of the solution. A single intravenous injection should be given for each attempt at treatment, and the patient should be observed for at least 24 hours. If a satisfactory clinical response does not occur after a reasonable period of time, discontinuation of therapy may be indicated.

Preparation of high dose corticosteroid therapy should be performed in a manner that will ensure the quality and safety of the therapy.

The final weight of dexamethasone sodium phosphate injection, 4 mg per mL, must be checked before use. If it is mixed with an infusion solution, sterile preparations should be used. Solution should be prepared as needed. Since absorption may be delayed by intramuscular administration, injections should be given at least 10 minutes after the administration of the solution. A single intravenous injection should be given for each attempt at treatment, and the patient should be observed for at least 24 hours. If a satisfactory clinical response does not occur after a reasonable period of time, discontinuation of therapy may be indicated.

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