ACTUAL SIZE(mm) : 98L x 185H

FRONT

DEXAMETHASONE SODIUM PHOSPHATE INJECTION B.P.

ELIDEXA 4mg/ml

Composition :
Each ml contains:
Dexamethasone Sodium Phosphate B.P.
Eq. to Dexamethasone Phosphate 4mg
Water for Injections B.P. q.s.

Excipients: Sodium Citrate, Sodium Metabisulphite, Methyl Paraben, Propyl Paraben, Di-Sodium EDTA, Sodium Hydroxide and Water for Injection.

Indications: Dexamethasone Phosphate is clinically indicated of Collagen Diseases, Pulmonary Disorders, Blood Disorders, Rheumatic Diseases, Skin Diseases, Gastrointestinal Disorders, Oedema, Eye Disorders, Neoplastic States, Endocrine Disorders. Dexamethasone Phosphate may be used in any surgical procedure when the adrenocortical reserve is doubtful. This includes the treatment of shock due to excessive blood loss during surgery.

PHARMACOLOGICAL PROPERTIES
Pharmacodynamic properties : Pharmacology of the corticosteroids is complex and the drugs affect almost all body systems. Maximum pharmacological activity lags behind peak blood concentrations, suggesting that most effects of the drugs result from modification of enzyme activity rather than from direct actions by the drugs.

Pharmacokinetic properties: Intramuscular injections of Dexamethasone sodium Phosphate gives maximum plasma concentrations of Dexamethasone at 1 hour. Dexamethasone is readily absorbed from the gastro-intestinal tract. Its biological half-life in plasma is about 190 minutes. Binding of Dexamethasone to plasma proteins is less than for most other corticosteroids. Dexamethasone penetrates into tissue fluids and cerebrospinal fluids. Metabolism of the drug takes place in the kidneys and liver and excretion is via the urine.

Adverse Reactions: High doses of Dexamethasone Phosphate are intended for short term therapy and therefore adverse reactions are uncommon. However, peptic ulceration and bronchospasm may occur.

Use in Pregnancy:
The ability of corticosteroids to cross the placenta varies between individual drugs, however, Dexamethasone Phosphate readily crosses the placenta. Administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate, intra-uterine growth retardation and affects on brain growth and development. There is no evidence that corticosteroids result in an increased incidence of congenital abnormalities, such as cleft palate/lip in man. However, when administered for prolonged periods or repeatedly during pregnancy, corticosteroids may increase the risk of intra-uterine growth retardation. Hypoadrenalism may, in theory, occur in the neonate following prenatal exposure to the corticosteroids but usually resolves spontaneously following birth and is rarely clinically important. As with all drugs, corticosteroids should only be prescribed when the benefits to the mother and child outweigh the risks. When corticosteroids are essential however, patients with normal pregnancies may be treated as though they were in the non-gravid state.

Use in Lactation :
Corticosteroids may pass into breast milk, although no data are available for Dexamethasone Phosphate. Infants of mothers taking high doses of systemic corticosteroids for prolonged periods may have a degree of adrenal suppression. Suppression of growth or other adverse effects may occur.

Dosage and Administration :
Dexamethasone Sodium Phosphate Injection, 4 mg/mL-For intravenous, intramuscular, intra-articular, intralesional and soft tissue injection.

Shock: of haemorrhagic, traumatic, surgical or septic origin; cerebral oedema associated with cerebral neoplasm; inflammatory diseases of joints and soft tissue such as rheumatoid arthritis.

BACK

	Adults	Children> 35 kg	Children < 35 kg
Initial dose	50 mg IV	25 mg IV	20 mg IV
1st day	8 mg IV every 2 hrs	4 mg IV every 2 hrs	4 mg IV every 3 hrs
2nd day	8 mg IV every 2 hrs	4 mg IV every 2 hrs	4 mg IV every 3 hrs
3rd day	8 mg IV every 2 hrs	4 mg IV every 2 hrs	4 mg IV every 3 hrs
4th day	4 mg IV every 2 hrs	4 mg IV every 4 hrs	4 mg IV every 6 hrs
5th– 8th day	4 mg IV every 4 hrs	4 mg IV every 6 hrs	2 mg IV every 6 hrs
After 8 days	Decrease by daily reduction of 4 mg	Decrease by daily reduction of 2 mg	Decrease by daily reduction of 1 mg

Children
Dosage requirements are variable and may have to be changed according to individual need. Usually 200 micrograms/kg to 400 micrograms/kg of body weight daily.
Corticosteroids cause growth retardation in infancy, childhood and adolescence, which may be irreversible. Treatment should be limited to the minimum dosage for the shortest possible time. In order to minimise suppression of the hypothalamic-pituitary-adrenal axis and growth retardation, treatment should be limited, where possible, to a single dose on alternate days.
Growth and development of infants and children on prolonged corticosteroid therapy should be carefully monitored.

Elderly
Treatment of elderly patients, particularly long-term, should be planned, bearing in mind the more serious consequences in old age. Such effects include osteoporosis, hypertension, hypokalaemia, diabetes, susceptibility to infection, thinning and fragility of the skin. Close clinical supervision is required to avoid life-threatening reactions.

Contraindications : Unless considered to be life-saving systemic administration of corticosteroids are generally contraindicated in patients with systemic infections, (unless specific anti-infective therapy is employed). Hypersensitivity to any components of the injection.

Overdose : Reports of acute toxicity and/or deaths following overdosage with glucocorticoids are rare. Exaggeration of corticosteroid related adverse effects may occur including hypertension, oedema, peptic ulceration, hyperglycaemia and altered mental state. Anaphylactic or hypersensitivity reactions may occur.

Warning and precautions*:*
Dexamethasone Sodium Phosphate Injection contains sodium sulfite, a sulfite that may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in nonasthmatic people. Corticosteroids may exacerbate systemic fungal infections and, therefore, should not be used in the presence of such infections unless they are needed to control drug reactions due to amphotericin B. Moreover, there have been cases reported in which concomitant use of amphotericin B and hydrocortisone was followed by cardiac enlargement and congestive failure.

Prolonged therapy, withdrawal of corticosteroids may result in symptoms of the corticosteroid withdrawal syndrome including fever, myalgia, arthralgia and malaise. This may occur in patients even without evidence of adrenal insufficiency.

There is an enhanced effect of corticosteroids in patients with hypothyroidism and in those with cirrhosis.

Corticosteroids should be used cautiously in patients with ocular herpes simplex for fear of 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 must be gradual.

Presentation :
2 ml Ampoule
Storage instructions:
Store in a cool place below 30º C. Protect from light. Do not freeze. Keep all Medicines out of reach of Children.

Manufactured by :
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