Gludex IM/IV Injection

Dexamethasone Sodium Phosphate USP 5 mg

Composition:

Each Ampoule (1 ml) contains Dexamethasone Sodium Phosphate USP 5 mg for IM/IV Injection.

Description:

Gludex contains Dexamethasone, which is a synthetically prepared glucocorticosteroid. Its main clinical application is as a steroidal anti-inflammatory agent. It acts on the Hypothalamic-Pituitary-Adrenal (HPA) axis at specific receptors on the plasma membrane. On other tissues it diffuses across cell membranes and complex with specific cytoplasmic receptors, which enter the cell nucleus and stimulate protein synthesis. It has anti-allergic, anti-toxic, anti-shock, anti-pyretic and immunosuppressive properties.

After 20 mg of intravenous administration, peak plasma level is reached within 5 minutes. The mean plasma half-life of Dexamethasone is 3.6+0.9 hours. It binds to plasma proteins, mainly albumin. Dexamethasone metabolism in the liver is slow and rather limited. Over 60% of the administered dose are excreted in the urine within 24 hours. Dexamethasone has only minimum mineralocorticoid activity, which makes it suitable for use in patients with cardiac failure or hypertension. Because of the long biological half-life (36-54 hours), Dexamethasone is especially suitable in conditions when continuous glucocorticoid action is desired.

Indications:

Rheumatoid arthritis, Collagen diseases, Inflammatory & allergic disorders, Anaphylactic shock, Cerebral oedema, Nausea & vomiting with chemotherapy, Acute adrenocortical insufficiency, Urticaria, Eczema, Skin diseases, Hyperplasia & hyperpyrexia, Gout.

Dosage & administration:

Dexamethasone Sodium Phosphate can be given parenterally at doses of 0.5-20 mg daily either as a single (slow) intravenous or intramascular injection or by intravenous infusion.

Large intravenous doses should be administered slowly to reduce the risk of cardiovascular collapse. The total daily intake of Dexamethasone, even in acute conditions should not exceed 80 mg except in certain very special circumstances.

Cerebral oedema: 10 mg initially by intravenous injection, then 4 mg by intramascular injection every 6 hours is required for 2-4 days then gradually reduced and stopped over 5-7 days.

Shock: By intravenous or intramascular injection or infusion 2-6 mg/kg, repeated if necessary after 2-6 hours.

Children: 0.25-0.5 mg/kg/body weight daily by slow IV injection or infusion.

Contraindication:

Ocular herpes simplex is an example of absolute contraindication to corticosteroid therapy. Relative contraindications are:

Gastrointestinal ulcer, acute or chronic infections, osteoporosis, pregnancy, diabetes mellitus, renal insufficiency, hypertension, history of psychotic illness, immediate before prophylactic immunization and finally hypersensitivity to Dexamethasone.

Adverse reaction:

Hypersensitivity including anaphylaxis and allergic skin reactions has been reported. The incidence of predictable undesirable effects of glucocoticoids correlates with the dosage timing of administration and duration of treatment. Patients on prolonged Dexamethasone therapy are at risk of collapse and possibly death if their daily dose is not increased at times of severe physical stress e.g. injury, surgery or infections. The somatic manifestations include growth retardation in children, osteoporosis and aseptic bone necrosis, peptic ulceration, ocular hypertension, subcapsular cataract, pancreatic disturbances and myopathy. Other Cushing-like features characteristic of glucocorticoid excess includes truncal obesity, moon-face, oedema, delayed wound healing, glaucoma and various psychiatric syndromes. These are all generally reversible with discontinuation of Dexamethasone treatment.

Precaution:

Dexamethasone should be used with caution in the presence of congestive heart failure or hypertension, in patients with diabetes mellitus, epilepsy, glaucoma, infectious disease, chronic renal failure and uraemia and in elderly persons.

Drug Interaction:

Dexamethasone exhibits interaction with phenytoin and phenobarbitone, ephedrine, rifampicin, magnesium trisilicate, salicylate, potassium depleting diuretics (such as thiazide or frusemide), cardiac glycosides, NSAIDs, anticoagulants, antidiabetics, antihypertensives, barbiturates, carbamazapine, primidone, antimuscarinic agents.

Pregnancy & Lactation:

Safety for use during pregnancy has not been established. Infants born of mothers who have received substantial doses of corticosteroids during pregnancy should be carefully observed for signs of hyperthyroidism. Corticosteroid appears in breast milk and may suppress growth, interfere with endogenous corticosteroid production or cause other untoward effects, so patient should stop nursing if drug is prescribed.

Pharmaceutical Precaution:

Keep in cool, dry place and away from light.

Warning:

Keep out of the reach of children.

Commercial Pack:

Box containing 2 x 5 ampoules of 1 ml in blister pack.

Manufactured by:

KEMIKO PHARMACEUTICALS LTD.
Bangladesh