Insert

DEXASONE
Injection
(Dexamethasone Sodium Phosphate)

Name and strength of active substance(s)
Dexamethasone Injection 5 mg/ml

Preservative:
Phenol 5 mg/ml.

Product description:
Dexasone Injection is a clear colorless sterile solution of Dexamethasone phosphate sodium eq. to Dexamethasone fill in glass ampoule.

Pharmacodynamics:
The glucocorticoid steroids actions are mainly anti-inflammatory, anti-allergic and anti-rheumatic, in conditions such as asthma and rheumatoid arthritis. It appears that a measure of a corticosteroids potency as glucocorticoid is the degree of inhibition of corticotrophin secretion it produces. Dexamethasone has immunosuppressant properties and can be administered to reduce immune response after organ transplant.

Phamacokinetics:
Dexasone Injection has rapid onset of action but of short duration. In the circulation, dexamethasone is bound to the plasma protein, but to a lesser extent than for other corticosteroids, mainly to globulin and less to albumin. The corticoid-binding globulin has high affinity low binding capacity, while the albumin had low affinity but large binding capacity. Only unbound dexamethasone has pharmacological effects or is metabolized. Corticosteroids diffuses into tissue fluids and cerebrospinal fluids but Trans placental diffusion in significant amounts had not been demonstrated. Corticosteroids are metabolized in the liver and kidney and excreted in the urine. The slower metabolism and lower protein binding affinity of dexamethasone may account for its increased potency compared with the natural corticosteroids. The biological half-life in plasma of dexamethasone is about 190 minutes.

Indication:
Severe allergic reactions, anaphylactic due to drugs, acute bronchial asthma, transfusion reactions, Steven-Johnson syndrome, acute dermatosis and laryngeal edema. Thyroid crisis and acute thyroiditis.
Adrenocortical insufficiency. Management of the symptoms and symptomatic relief of rheumatoid arthritis, rheumatic fever, status asthmaticus, other inflammatory conditions and ulcerative colitis. It is useful in the treatment of nephritic oedema as it can produce diuresis.

Recommended Dosage:
Intramuscular injection or slow intravenous injections of 4 to 20 mg depending on the severity of the condition and repeated as may be necessary every 3 to 4 hours. The total daily dose should not exceed 50 mg. The dose may be reduced to half the initial dose when the acute stage has passed and substitute with Dexasone Tablets as soon as feasible. Dexasone Injection may be injected into joints but not the intervertebral joints.

Route of administration:
Dexasone Injection may be administered by intramuscular or intravenous injection for intensive therapy or in emergencies.

Contraindications:
Care should be taken in treating diabetic patients, as insulin requirements are usually increased during administration of dexamethasone. Dexamethasone should be avoided when tuberculosis is present and care should be taken when infections are present, particular systemic fungal or herpes infections. Dexamethasone should not to be used in pregnancy particularly within the first 14 weeks and only used with caution in nursing mothers. Caution should also be exercised in cases of renal insufficiency, diverticulitis, fresh intestinal anastomosis, active or latent peptic ulcer, hypertension, thromboembolic tendencies, psychotic tendencies, and myasthenia gravis.

Warning and Precautions:
Care should be taken in treating diabetic patients, as insulin requirements are usually increased during administration of dexamethasone patients should be warned of this particularly those who self-administered insulin.

Interactions with other medicaments:
Alcohol or other anti-inflammatory drugs may increase ulcer genic effects when used concurrently with dexamethasone. Amphotericin B or Potassium-depleting diuretics with dexamethasone may enhance hypokalemia. Oral anticoagulant effects may be increased or decreased when used concurrently with dexamethasone. Cardiac glycosides concurrent used with dexamethasone may enhance the possibility of arrhythmias.

Statement on usage during pregnancy and lactation:
Dexamethasone cross the placenta. Usage in pregnancy must be considered since studies in animals have shown that dexamethasone cause teratogenicity.

Adverse-effects:
Sodium retention, oedema, electrolyte imbalance and Cushing's syndrome. Withdrawal syndrome and Aggravation of fungal and Herpes infection.

Symptoms and Treatment of Overdose:
Overdosage are comparatively rare and if ingested, emetic may be of help. Gastric lavage may also be of value. Due to its low protein binding affinity, peritoneal dialysis may be instituted.

In compatibilities:
Problems have not been documented.

Storage condition:
Store below 30ºC
Protect from light.

Dosage forms and packaging available:
Pack of 50 x 1ml per box.

Manufacturer:
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Product Registration Holder:
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