Sonexa 6

Dexamethasone USP

Composition:
Sonexa 6 Tablet: Each film coated tablet contains Dexamethasone USP 6 mg.
Sonexa 6 Injection: Each 1 ml ampoule contains Dexamethasone Sodium Phosphate USP equivalent to Dexamethasone 6 mg.

Pharmacology:
Sonexa contains Dexamethasone which is a synthetically prepared glucocorticosteroid. Its main clinical applications are as a steroidal anti-inflammatory agent. It acts on the Hypothalamic-pituitary-adrenal (HPA) at specific receptors on the plasma membrane. On other tissues it diffuses across cell membranes and complex with specific cytoplasmic receptors, which e nter the cell nucleus and stimulate protein synthesis. It has anti-allergic anti-toxic, anti-shock, anti-pyretic and immunosuppressive properties. After 20 mg 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 protiens, 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:
1. Rheumatoid arthritis
2. Collagen diseases
3. Inflammatory & allergic disorders
4. Anaphylactic shock
5. Cerebral oedema
6. Nausea & vomiting with chemotherapy
7. Acute adrenocortical insufficiency
8. Urticaria
9. Eczema
10. Skin diseases
11. Hyperplasia & hyperpyrexia
12. Gout

Dosage & administration:
Sonexa 6 Tablet: The initial dosage of Dexamethasone varies from 0.75 to 9 mg per day. In general, corticosteroids dosage depends on the severity of the condition and the response of the patient.
Sonexa 6 Injection: 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 2-10 days.
Shock: By intravenous or intramascular injection or infusion 2-6 mg/Kg, repeated if necessary after 2-6 hours.

The dose in children varies from 0.03 to 0.09 mg per Kg body weight twice a day for adrenal suppression and between 0.01 mg per Kg body weight once a day for other indications. An alternate-day regimen reduces the risk of growth retardation.

Contraindications:
Ocular herpes simplex is an example of absolute contraindication to corticosteroid therapy relative contraindications are:
Gastro-intestinal 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.

Side effects:
Hypersensitivity including anaphylaxis and allergic skin reactions have been reported. The incidence of predictable undesirable effects of glucocorticoids 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 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.

Precautions:
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 uremia and in elderly persons.

Drug interactions:
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, carbamazepine, primidone, antimuscarinic agents.

Use in special group:
Use in pregnancy: 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.
Use in lactation: 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.

Storage:
Store below 30^0 C. Keep in dry place & protect from light. Keep out of reach of children.

Packing:
Sonexa 6 Tablet: Each box contains 30 tablets in Alu-PVC blister pack.
Sonexa 6 Injection: Each box contains 10 ampoules in Alu-PVC blister pack.

Manufactured by:
ARISTOPHARMA LTD.
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