Sonexa 4

Dexamethasone USP 4 mg

COMPOSITION
Each film coated tablet contains Dexamethasone USP 4 mg.

CLINICAL PHARMACOLOGY
Mechanism of action: Dexamethasone is a corticosteroid exhibiting both anti-inflammatory and immune suppressant properties. It prevents the functions of phospholipase A_2 and thereby causing anti-inflammatory action. It also interferes in the function of mediators of inflammatory response, and causes suppression of immune responses.
Pharmacokinetics: Dexamethasone is readily absorbed from the gastro-intestinal tract. It extensively binds to plasma proteins, mainly to globulin. It is metabolized mainly in the liver but also in the kidney. It is excreted in the urine and has a $t_{1/2}$ of approximately 190 minutes.

INDICATIONS
Sonexa 4 tablet is indicated for the pretreatment for chemotherapy to reduce delayed inflammation and side effects associated with chemotherapy. It is indicated for the prevention of nausea and vomiting associated with Cisplatin based highly emetogenic chemotherapy, and moderately emetogenic chemotherapy and combinations of Anthracycline and Cyclophosphamide.

DOSAGE AND ADMINISTRATIONS
The recommended dosage of Sonexa 4 tablet is as following table for the prevention of delayed inflammation and side effects associated with chemotherapy:
Cisplatin-based highly emetogenic cancer chemotherapy -

	Day 1	Day 2	Day 3	Day 4
Dexamethasone	20 mg; 30 min prior to chemotherapy.	8 mg twice daily	8 mg twice daily	8 mg twice daily
Rolapitant	180 mg; Approximately 1-2 hours prior to chemotherapy.	None		
5-HT_3 receptor antagonist.	See the prescribing information for the co-administered 5-HT_3 receptor antagonist for appropriate dosing information.	None		

Moderately emetogenic cancer chemotherapy and combinations of Anthracycline and Cyclophosphamide -

	Day 1	Day 2	Day 3	Day 4
Dexamethasone	20 mg; 30 min prior to chemotherapy.	None		
Rolapitant	180 mg; Approximately 1-2 hours prior to chemotherapy.	None		
5-HT_3 receptor antagonist.	See the prescribing information for the co-administered 5-HT_3 receptor antagonist for appropriate dosing information.			

CONTRAINDICATIONS
Dexamethasone is contraindicated in patients who are hypersensitive to any components of this product. It is also contraindicated in patients with systemic infections unless specific anti-infective therapy given or live virus immunization.

SIDE EFFECTS
Gastro-intestinal: Dyspepsia, nausea, peptic ulceration, abdominal distension, abdominal pain, diarrhoea, oesophageal ulceration, oesophageal candidiasis and acute pancreatitis. Musculoskeletal: Proximal myopathy and osteoporosis. Endocrine: Suppression of the hypothalamo-pituitary adrenal axis; growth suppression in infancy, childhood and adolescence; menstrual irregularity; amenorrhoea and cushingoid faces. Nervous system: Depression, insomnia and dizziness. Eye disorders: Increased intra-ocular pressure and glaucoma. Immunosuppressive effects: Increased susceptibility to and severity of infections.

PRECAUTIONS
Caution is necessary in patients with the following conditions: Hypertension, hypothyroidism, recent congestive heart or liver failure, renal insufficiency, diabetes mellitus, osteoporosis, glaucoma, steroid induced psychoses, epilepsy and seizure disorder, peptic ulceration, previous steroid myopathy and tuberculosis. Caution is also necessary for patients with thromboembolic disorders, Duchenne's muscular dystrophy, Cushing's disease and patients with myasthenia gravis receiving anticholinesterase therapy.

DRUG INTERACTIONS
CYP3A4 inducers: Phenobarbital, phenytoin, rifampicin, rifabutin, carbamazepine, primidone and aminoglutethimide may reduce the efficacy of dexamethasone. CYP3A4 inhibitors: Ketoconazole, ciclosporin or ritonavir may decrease dexamethasone clearance. Dose adjustment may be considered for any concurrent anti-diabetic therapy as corticosteroids may increase blood glucose level. Concomitant administration of NSAIDs with corticosteroids may increase the risk of GI ulceration. Concurrent use of antacids may decrease the absorption of corticosteroids. Response to anticoagulants may be reduced or less often enhanced by corticosteroids. The risk of hypokalaemia may be increased with amphoteracin. Eestrogens may potentiate the effects of glucocorticoids. The growth promoting effects of somatotropin may be inhibited.

PREGNANCY AND LACTATION
Dexamethasone readily crosses the placenta and it may excrete into breast milk. Dexamethasone should only be prescribed when the benefits to the mother and child outweigh the risks.

PEDIATRIC AND GERIATRIC USE
Long-term use should be avoided as it causes growth retardation in infancy, childhood and adolescence. Elderly patients are more susceptible to the side effects; therefore long-term use should be planned with caution.

HEPATIC AND RENAL INSUFFICIENCY
Therapy with Dexamethasone should be used with great caution in these patients.

OVERDOSE
Supportive and symptomatic therapy should be given in case of overdose.

STORAGE
Store below 30^0C, keep in dry place & protect from light. keep out of the reach of children.

PACKAGING
Sonexa 4 Tablet: Each box contains 20 tablets in blister pack.

Manufactured by:
ARISTOPHARMA LTD.
Shampur-Kadamtali I/A, Dhaka-Bangladesh

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